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SURGICAL AUDIT OF THE DEPARTMENT OF SURGERY IN A TERTIARY CARE CENTRE: INCIDENCE OF SSI AND OTHER COMPLICATIONS WITH IMPLEMENTATION OF WHO SURGICAL SAFETY CHECKLIST

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INTRODUCTION

INTRODUCTION

A surgical audit is a vital strategy for upholding standards in surgical care within hospitals. It involves a systematic and critical analysis of the quality of surgical care, assessed by peers against explicit criteria or recognized standards. The findings are then utilized to inform and enhance surgical practices, ultimately improving patient care. Maintaining this standard should encourage hospital administrators to allocate adequate resources to support these essential activities.(1) In surgery, this process serves as a systematic approach to reviewing clinical practice, allowing for the identification of areas of excellence as well as opportunities for improvement.(2)

The word “audit” comes from the Latin word “audire”, meaning “to hear”.(3) Clinical audit is defined as “a quality improvement process aimed at enhancing patient care and outcomes through a systematic review of clinical practices against established criteria. Where necessary, changes are implemented, followed by ongoing monitoring to ensure continuous improvement in healthcare delivery."(4) Adapting an audit system to the diverse field of surgery enables the analysis of large datasets and the identification of areas for clinical improvement. It can assist in estimating workload, identifying common challenges, and planning effective management strategies for the future.(5) A historical review of audits reveals that the objectives and roles of auditors have continuously evolved over time.(6)

Developing countries should conduct regular clinical audits to identify gaps in routine clinical practice and implement improvements, aligning with the standards of developed nations. It is essential to recognize audits as a fundamental component of research methodology. By enhancing the evaluation of healthcare management’s structure, processes, and outcomes, audits can play a crucial role in improving overall healthcare quality. Integrating audit practices into all healthcare professional programs and organizational levels will help establish a system that adheres to standard-based medicine while ensuring timely updates to guidelines and protocols.(5)

More than 310 million surgical procedures are performed worldwide annually.(7) Estimates of morbidity and mortality vary.(8–10) However, recent data suggest that approximately 75 million patients experience postoperative complications annually, resulting in an estimated two million deaths worldwide.(11,12)

Checklists provide a simple, effective, and reproducible method for standardizing key aspects of patient care. The World Health Organization (WHO) Surgical Safety Checklist is the most widely adopted surgical checklist, consisting of 19 items across three critical phases: before the induction of anesthesia, before the surgical incision, and before the patient exits the operating theater. These checks encompass essential actions such as verifying patient identity, introducing all team members, and ensuring appropriate antibiotic prophylaxis.(13) Since its introduction, the checklist has been adopted by more than 4,000 hospitals worldwide and is now recognized as a surrogate marker for the quality of patient care.(14,15)

NEED FOR STUDY

- Understanding whether the SSC reduces complication rates in general surgery at a tertiary care hospital is crucial for improving patient safety.
- While studies in high-income countries show a reduction in mortality and complications with SSC use, evidence from tertiary care centers in developing settings is scarce.
- A well-conducted surgical audit will provide data-driven insights on whether checklist adherence correlates with improved postoperative outcomes.
- As the WHO emphasizes safe surgery as a global priority, this study will add context-specific evidence to ongoing discussions on improving surgical safety in tertiary hospitals.
- Results can be benchmarked against international studies to highlight best practices and areas needing improvement.

In conclusion,

This study is necessary to evaluate the effectiveness of the WHO SSC in reducing postoperative complications and to identify barriers affecting its implementation in a tertiary care hospital. A surgical audit will provide evidence-based recommendations for improving compliance, enhancing patient outcomes, and strengthening institutional surgical safety policies.

AIM AND OBJECTIVES

AIMS AND OBJECTIVES

The aim of this audit is to enable improvements in patient care as a result of a successful audit with following objective:

- To correlate the implementation of the WHO Surgical Safety Checklist with incidence of post op complications including SSI.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Surgical Audit: Definition, Purpose, and Process

A surgical audit is defined as "an unbiased, systematic and critical analysis of the quality of surgical care, reviewed by peer(s) against explicit criteria or recognised standards. The purpose of an audit is to examine whether what you think is happening really is, and whether audited outcomes meet existing standards."(16)

A surgical audit is an essential mechanism for improving surgical care through the systematic evaluation of clinical practices. One of its primary goals is to enhance and maintain the quality of patient care by identifying both strengths and areas in need of improvement, allowing surgical procedures to be refined for better clinical outcomes. In addition, audits support the continuous education of surgeons by offering valuable insights into performance, which fosters professional growth and helps surgical teams remain aligned with current best practices. Moreover, surgical audits contribute to optimizing the use of healthcare resources by evaluating how efficiently and effectively they are being utilized. This ensures that the delivery of surgical services is both cost-effective and patient-centered, ultimately improving overall healthcare outcomes.

- Role of audits in quality improvement and patient safety

  Audits play a vital role in enhancing quality improvement and patient safety by systematically evaluating healthcare practices against established standards. By identifying gaps in care and providing actionable insights, audits facilitate targeted improvements that enhance patient outcomes and mitigate risks. Functioning as a monitoring mechanism, audits ensure that healthcare delivery remains aligned with best practices and safety protocols.(17)

  Key Contributions of Audits to Quality Improvement and Patient Safety:

- Identification of Areas for Improvement: Audits systematically analyze data from patient records, clinical workflows, and healthcare processes to identify deviations from established guidelines. This enables the early detection of factors contributing to adverse events or suboptimal outcomes.(18)

- Data-Driven Decision-Making: By providing quantitative performance metrics, audits empower healthcare providers to make informed decisions regarding quality improvement initiatives and resource allocation.

- Facilitation of a Continuous Improvement Cycle: Audits follow a structured, iterative process in which initial assessments lead to targeted interventions. Subsequent re-evaluations measure the effectiveness of these interventions, ensuring sustained improvements in care quality.(19,20)

- Promotion of a Culture of Safety: When conducted with an emphasis on system-level enhancements rather than individual fault, audits foster a culture of safety. This encourages healthcare professionals to report errors and near misses, promoting proactive risk management and patient safety.(21)

- Establishment of Standardized Care Practices: Audits contribute to the development and reinforcement of clear clinical standards by defining expected levels of care and evaluating performance against these benchmarks.(22,23)

  By integrating audits into routine healthcare operations, organizations can drive continuous quality improvement, enhance patient safety, and ensure adherence to best practices in clinical care.

Considerations

- **Clear Objectives:** Establishing well-defined goals and measurable indicators is essential for ensuring a structured and focused audit process. Objectives should be specific, achievable, and aligned with broader quality improvement initiatives. By setting clear expectations, audits can effectively assess performance, identify gaps, and guide targeted interventions to enhance patient care.(24,25)

- **Stakeholder Involvement:**
  Active participation from healthcare professionals across all levels—including physicians, nurses, administrators, and support staff—is crucial for the success

of an audit. Engaging stakeholders fosters collaboration, enhances commitment, and promotes a sense of ownership over quality improvement initiatives. Involving frontline staff ensures that audits reflect real-world challenges and lead to practical, implementable solutions.

- **Feedback Loop:** Providing timely, data-driven feedback to healthcare teams is fundamental to driving meaningful improvements. Audit findings should be communicated clearly and constructively, highlighting both areas of success and those requiring attention. Regular feedback allows for immediate corrective actions, promotes accountability, and reinforces a culture of continuous learning and improvement. Additionally, follow-up assessments should be conducted to measure progress and ensure the sustainability of implemented changes.(26)

Historical background and evolution of surgical audits

Surgical audits have been a cornerstone of surgical practice for centuries, serving as a means to evaluate and improve patient care. While early audits were informal discussions among surgeons, modern auditing methods have evolved into structured, data-driven processes that provide valuable insights into surgical outcomes. The primary objective of surgical audits is to assess the quality of surgical care, identify areas for improvement, and implement necessary changes to enhance patient safety and clinical efficiency.(27,28)

The Emergence of Early Surgical Audits

- Historically, surgical audits were conducted as "polite, restrained discussions" among surgeons, focusing on case reviews and sharing experiences to refine surgical techniques.(27,29)

- In 1953, the American College of Surgeons initiated a research program to develop a structured surgical audit system, laying the foundation for modern surgical evaluations.(30)

- The POSSUM (Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity) audit system, introduced in the

1980s, provided a standardized scoring method to assess surgical quality, predict patient outcomes, and measure morbidity and mortality risks.(31)

Advancements in Modern Surgical Audits

Modern surgical audits have evolved significantly, moving away from purely anecdotal evaluations to embrace a more quantitative, evidence-based approach. These contemporary audits rely on large datasets encompassing mortality rates, postoperative complications, and patient recovery outcomes, allowing healthcare providers to benchmark their performance against both institutional and national standards. In doing so, audits serve as a critical tool for identifying and managing clinical risks, playing a vital role in safeguarding not only patient safety but also the well-being of healthcare personnel. Furthermore, the scope of surgical audits has broadened beyond individual surgical outcomes to include institutional-level evaluations, assessing compliance with national and international healthcare regulations. This wider application promotes greater accountability and consistency in surgical care across all levels of the health system.(32)

Surgical audits play a pivotal role in shaping healthcare policies and refining surgical practices. One of their core objectives is to enhance the quality of patient care by systematically evaluating surgical performance, allowing for the identification of best practices and pinpointing areas that require improvement to ensure optimal outcomes. Additionally, audits are essential in reducing clinical risks and complications, as they facilitate regular reviews of surgical procedures to minimize preventable errors and protect both patients and healthcare providers. They also serve as a tool for evaluating healthcare institutions, measuring compliance with established medical standards and ensuring that hospitals and surgical centers maintain consistent quality across their services. Furthermore, surgical audits help identify opportunities for continuous improvement by analyzing trends in outcomes, which can inform advancements in surgical techniques, guide efficient resource allocation, and improve overall patient management. By embedding modern audit practices into routine surgical workflows, healthcare institutions promote a culture centered on continuous learning, patient safety, and evidence-based decision-making, ultimately raising the global standard of surgical care.

Educational Opportunities Provided by Surgical Audits

Surgical audits offer valuable educational benefits for surgeons by promoting professional development, enhancing clinical decision-making, and supporting continuous learning. They encourage collaboration among surgeons and healthcare staff, leading to the exchange of knowledge and refinement of clinical attitudes and approaches. Audits also improve critical thinking and support evidence-based practice by systematically evaluating surgical outcomes and guiding local quality improvements. They provide opportunities to assess new technologies and procedures, ensuring their effectiveness before integration into practice. Furthermore, audits help identify gaps in knowledge and skills, leading to targeted training programs that address these deficiencies. By establishing expected levels of care, surgical audits guide teams in maintaining high standards of clinical practice. Overall, incorporating surgical audits into routine practice improves not only patient outcomes but also the educational environment, supporting the ongoing growth and learning of surgical professionals.

Steps of a Surgical Audit

A surgical audit is a structured and multifaceted process designed to evaluate and enhance surgical practices. It begins with the collection and measurement of clinical activities and outcomes, which involves systematically documenting details such as the types of surgical procedures performed, patient responses, the incidence of complications, and recovery times. This data serves as the foundation for assessing the effectiveness and quality of surgical care. Once collected, the information undergoes analysis and comparison against established standards, performance indicators, and outcome parameters. This comparative assessment helps identify deviations from expected norms, uncovering gaps in practice that may require attention. A vital component of the audit process is the peer review mechanism, where surgeons and other healthcare professionals review each other's work in a constructive, collegial manner. This review is complemented by a feedback loop that provides specific, actionable insights aimed at addressing deficiencies and promoting continuous improvement in surgical performance. Together, these steps ensure that surgical audits drive meaningful, data-informed advancements in clinical practice.

Types of Surgical Audits

Surgical audits can be conducted at various levels—ranging from personal and departmental to hospital-wide—and can be tailored to evaluate different aspects of surgical practice. Among the key types is the Total Practice Audit, which reviews all surgical procedures performed over a set period. This comprehensive approach offers a broad perspective on overall surgical activity, enabling the identification of recurring patterns and areas in need of improvement. In contrast, a Selected Audit targets a specific surgical procedure or patient subgroup, focusing on cases conducted within a defined timeframe. This helps ensure that outcomes for that particular procedure meet accepted clinical standards. A Clinical Unit Audit is typically carried out by an individual department or unit and involves a smaller cohort of surgeons. It examines internal performance metrics, supporting localized improvements in surgical processes. An Outcome Audit concentrates on the postoperative results of surgeries—such as complications, infections, patient mortality, or delayed recovery—helping assess procedural safety and effectiveness while guiding strategies to enhance patient care. Lastly, a Quality Improvement Audit is designed to measure the overall quality and efficiency of surgical services. It evaluates aspects such as patient satisfaction, operational performance, and cost-effectiveness. This type of audit plays a crucial role in improving patient care and hospital resource management by identifying areas for service enhancement and more judicious use of institutional assets.

Effective surgical audit

Establishing a culture of surgical audit requires addressing potential resistance and misconceptions among healthcare professionals. Audits should be conducted in a safe, non-threatening environment that emphasizes their educational value. Promoting a ‘no blame’ culture encourages open discussion, self-reflection, and honest feedback, which are critical to improving outcomes. A supportive atmosphere depends on both social and physical factors within the healthcare setting. Clinical outcome audits are essential to ensure high-quality care and have become key tools in risk management. To ensure audits are not viewed as burdensome, data collection should be embedded in routine clinical documentation. As technology advances, this integration reduces repetitive tasks. Adequate support is necessary for effective data collection, and

hospitals should prioritize this, given its significance in professional development and credentialing. Data collection should focus on essential information, with clear responsibility for accuracy and validation. Regular data reviews ensure quality and integrity, supported by active clinician involvement. Moreover, audits must result in action. Feedback should lead to practical changes through cooperation between surgeons and administrators. Emphasis must be placed on establishing systems that link audit findings to quality improvement and safety. When audit culture is nurtured, supported with resources, and followed by implementation, it becomes a powerful tool for enhancing clinical outcomes and patient safety.

The Surgical Audit Cycle

For an audit to be successful, proper planning and preparation are crucial. These steps may vary based on the type of audit being conducted. Engaging with key participants, selecting an appropriate audit topic, and determining how the audit will be executed across a hospital, practice, or multicenter setting are all vital factors to consider.

Surgical audits generally follow a five-step cycle:

1. **Step 1: Determine Scope** – Identify the specific focus of the audit, such as the types of surgeries, patient groups, or time frames involved.

2. **Step 2: Define Standards** – Establish the standards or benchmarks against which the surgical procedures or outcomes will be measured.

3. **Step 3: Collect Data** – Gather relevant data based on the defined scope and standards, ensuring it is comprehensive and accurate.

4. **Step 4: Present and Interpret Results (with Peer Review)** – Share the collected data, interpret the findings, and involve peer review to assess the outcomes and discuss areas for improvement.

5. **Step 5: Make Changes and Monitor Progress** – Based on the findings, implement necessary changes to improve practice, and continuously monitor progress to ensure that improvements are sustained.

This structured cycle helps ensure that the surgical audit is thorough, objective, and ultimately effective in improving surgical outcomes and practices.

Step 1: Define the Scope

Before initiating a surgical audit, it is essential to clearly define its scope to ensure the process remains focused and effective. The scope sets boundaries for what the audit will evaluate and ensures alignment with its objectives, reducing the likelihood of gathering irrelevant or excessive data. Defining specific problems or areas of concern early on helps determine the appropriate type of audit and keeps the process efficient and purposeful. For the audit findings to be statistically meaningful and credible, a sufficient number of cases must be reviewed. If a clinical unit performs a limited number of a certain procedure annually, the results should be compared with larger datasets—such as findings from published literature, professional groups, or colleagues with greater experience in that procedure—to generate more reliable insights and enhance the audit's significance.

Surgical audits often target specific focus areas to evaluate the quality and outcomes of care. One common metric is 30-day mortality, which tracks the number of patients who die within thirty days following surgery to assess immediate outcomes. Length of hospital stay is another key focus, used to evaluate recovery efficiency and overall hospital performance. Unplanned readmissions—patients who return to the hospital after discharge—may point to postoperative complications or shortcomings in follow-up care. Similarly, unplanned return to theatre highlights complications necessitating reoperation, serving as a quality marker for surgical safety and success.

Audits also assess positive and negative outcomes, identifying both favorable results and complications that could guide improvements in technique or perioperative care. Evaluating surgery-specific complications, such as infections, hemorrhage, or damage to surrounding tissues, helps pinpoint risks tied to certain procedures. Another critical component is reviewing the care process, including preoperative evaluations, intraoperative practices, and postoperative recovery protocols, to ensure comprehensive and standardized care throughout the surgical pathway.

Waiting times for surgery or outpatient appointments are also examined to detect inefficiencies in scheduling or resource allocation. Audits may also assess the use of diagnostic tests, verifying whether imaging, laboratory tests, or other diagnostics were used appropriately and contributed meaningfully to patient care. Patient satisfaction plays a major role in evaluating outcomes, with feedback gathered through tools like Patient-Reported Outcome Measures (PROMs), which reflect patients' perspectives on their recovery, pain, mobility, and overall quality of life following surgery.

Another important focus area is the administration of prophylactic antibiotics, ensuring that antibiotics are delivered at the correct time and in the proper dosage to minimize the risk of surgical site infections. While surgical audits often emphasize adverse outcomes, they must also seek to identify and address systemic issues affecting patient care, such as protocol inconsistencies, resource limitations, or training needs.

Beyond identifying areas for improvement, audits should also highlight positive outcomes and successes, celebrating instances of effective care delivery and exemplary surgical performance. Recognizing achievements promotes a balanced audit culture, motivates clinical teams, and reinforces high standards. Ultimately, audits should not only detect errors but also serve as instruments of continuous quality improvement, fostering a healthcare environment focused on learning, reflection, and excellence in patient care.

Step 2: Define Standards

After clearly defining the scope of a surgical audit, the next critical step is to establish the standards that will be used for evaluation. These standards function as benchmarks, allowing surgical practices and outcomes to be assessed objectively. It is essential that the selected standards are relevant, comprehensive, and achievable so that the audit yields meaningful and actionable insights. There are several methods to determine appropriate standards. One approach involves utilizing existing evidence-based research and established clinical guidelines. Alternatively, locally adapted protocols may be used if they better reflect the specific needs and capabilities of the

institution. Input from relevant specialty groups may also be valuable in setting appropriate and realistic standards for the procedures under review.

Transparency in the selection or creation of standards is key to ensuring consistency and clarity throughout the audit process. The standards must be well-defined and align with measurable indicators. To ensure they are effective, each standard should meet three essential criteria: measurability, specificity, and realism. Measurability ensures that the standard can be assessed using reliable data, offering a way to compare current performance with desired outcomes. Specificity requires the standards to be detailed and unambiguous, which reduces confusion and enhances the precision of the audit process. Realism ensures that standards are achievable within the existing context, including the institution's resources, patient population, and available personnel. Unattainable standards may compromise the credibility of the audit and demotivate staff.

When establishing or revising standards, it is helpful to ask key guiding questions. First, can the necessary data be collected and compared accurately to the proposed standards? This determines the practicality of evaluating performance based on the available data sources. Second, is there a clear understanding of what constitutes good practice in the area being audited? Knowing what best practice looks like allows the standard to be set at a meaningful and realistic level of quality. Lastly, are there any foreseeable barriers that might hinder the achievement of these standards? Identifying obstacles, such as limitations in resources, staffing issues, or patient-specific challenges, helps in refining the standards to make them more attainable and practical. These questions provide a reality check and promote the development of useful, focused standards.

By developing standards that are evidence-based, measurable, specific, and realistically achievable, auditors ensure that the audit process remains constructive and goal-oriented. These standards provide a strong framework for data collection, analysis, and comparison, enabling the identification of gaps and driving improvements in surgical practice. Ultimately, the effectiveness of a surgical audit depends not just on data collection or scope but on the strength of the standards guiding the entire evaluation. With clear and well-formulated benchmarks, the audit is

more likely to result in practical recommendations that enhance patient care and institutional performance.

Clinical indicators

Clinical indicators are measurable components of clinical care that offer a structured approach to evaluating the quality and safety of healthcare services over time. Regular monitoring and review of these indicators are vital to ensure they remain relevant to healthcare professionals, accurately reflect the evolving healthcare landscape, and possess clearly defined guidelines for data collection and reporting. These standards should be established through professional consensus to ensure consistency and credibility. Importantly, clinical indicators should be recognized not only as metrics but as integral tools for continuous quality improvement. By consistently updating and refining these indicators, healthcare institutions can promote better patient outcomes and implement evidence-based enhancements in care delivery, thereby strengthening overall clinical performance.

Characteristics of a Well-Designed Clinical Indicator

A well-designed clinical indicator acts as a valuable screening tool, used to identify, flag, or draw attention to specific clinical concerns that could impact patient care. These indicators play a crucial role in recognizing trends, detecting variations in practice, and pinpointing potential problem areas within healthcare systems. Most commonly, clinical indicators are rate-based, meaning they measure how frequently a particular event occurs within a defined population over a specified time period. However, clinical indicators are not designed to provide absolute answers; instead, they serve as signals—highlighting where further analysis and investigation may be necessary. This often becomes evident when statistical outliers or significant deviations from expected benchmarks are observed.

For instance, an indicator tracking hospital-acquired infections might measure the proportion of patients who develop infections following surgical procedures. If this rate rises unexpectedly compared to historical trends or national benchmarks, it could indicate a breakdown in infection control measures. Such a signal would then prompt

a comprehensive review of hygiene practices, operative protocols, or the administration of prophylactic antibiotics to uncover any underlying deficiencies.

Clinical indicators are instrumental in assessing the overall quality of care delivered, comparing institutional performance, and identifying areas for improvement. They serve as a foundation for evaluating whether current practices align with established standards and help facilitate informed, data-driven decision-making by clinicians and administrators alike.

The most effective clinical indicators possess several key qualities. They must be derived from objective and independent data collection processes to ensure accuracy and reliability. They should also convey meaningful clinical information that resonates with healthcare professionals and inspires confidence in their validity. Additionally, the indicators should prompt thoughtful reflection and a proactive response, encouraging providers to explore and address any deviations from expected norms. Importantly, these indicators should not be limited to measuring clinical outcomes or procedural processes but should also include structural components—such as rates of hospital-initiated surgery postponements and patient wait times—that reflect the system's accessibility, responsiveness, and efficiency.

By employing well-structured and clinically meaningful indicators, healthcare institutions can better monitor performance, reduce patient risk, and promote continuous improvement in both care delivery and system operations.

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Adverse Events and Complications

The collection and analysis of data on adverse events and complications are fundamental to clinical audits and quality improvement initiatives. While these terms are often used interchangeably, they represent distinct concepts in patient care.

An adverse event refers to an unintended injury or harm caused by medical management rather than the patient's underlying condition. It is typically preventable or linked to system failures, human error, or lapses in care. Examples include medication errors leading to severe allergic reactions or surgical procedures performed on the wrong site.

A complication, on the other hand, is an undesirable outcome that arises as a known risk of a medical procedure or treatment. Some complications are considered inevitable, occurring despite adherence to best practices. For instance, a certain percentage of patients undergoing major abdominal surgery may develop post-operative infections, even when strict infection control measures are followed.

The key distinction between the two is the concept of "unintentional harm." While all adverse events result in unintended harm, not all complications qualify as adverse events. Complications may be expected risks of treatment, whereas adverse events typically indicate a departure from optimal care.

By systematically tracking and analyzing both complications and adverse events, healthcare providers can identify trends, implement targeted interventions, and enhance patient safety while ensuring that quality improvement efforts are focused on preventable harm.

Adverse Events in Healthcare

An adverse event is defined as unintentional harm resulting from medical care rather than the underlying disease process. These events can range from minor complications to severe, life-threatening incidents.

Major adverse events such as bile duct injuries, anastomotic leaks, and unplanned reoperations should be systematically documented and reviewed through structured peer discussions, including morbidity and mortality (M&M) meetings. These sessions provide opportunities to analyze contributing factors, identify system-level issues, and guide improvements in clinical practice. Although less severe, minor adverse events—such as pneumonia or urinary tract infections (UTIs)—still hold clinical significance. While they may not always require detailed discussion in audit meetings, they should be consistently recorded and monitored for patterns or emerging trends.

Understanding the origin of adverse outcomes is essential for distinguishing preventable complications from those considered acceptable or inevitable within clinical practice. Adverse outcomes may result from a variety of causes, including technical errors during surgery, patient-specific factors such as underlying comorbidities, progression of disease, or complications that fall within recognized risk thresholds for certain procedures. These insights enable targeted quality improvement measures that address both individual and systemic shortcomings.

To ensure a structured and consistent review of such events, many institutions implement Limited Adverse Occurrence Screening (LAOS), a focused evaluation strategy that targets specific reportable adverse events. This allows audit teams to direct attention toward high-impact occurrences while maintaining an efficient review process.

Several key adverse events merit continuous tracking and, where appropriate, inclusion in formal audits. These include surgical patient mortality, unplanned readmission within 28 days, unexpected transfer back to intensive care from a general ward, unplanned reoperations, and unanticipated blood transfusions. Additionally, transfers for specialized care, severe complications graded as 3 or 4, complications that significantly prolong hospital stays, and accidental organ perforations are all important indicators of clinical risk. Other events of concern include serious drug reactions, medication errors, cardiac or respiratory arrest, Medical Emergency Team (MET) activations, patient falls, pressure sores, hospital-acquired infections, and the same-day cancellation of scheduled surgeries.

Most healthcare institutions already track many of these events as part of their internal reporting systems. However, a key responsibility of clinical audit teams is to ensure that data on critical occurrences—such as nosocomial infections, falls, pressure ulcers, and drug-related errors—are communicated effectively to surgical teams. When discussed appropriately, these events can drive awareness and facilitate targeted interventions. Maintaining transparency and fostering open communication about adverse outcomes is crucial for promoting patient safety and reinforcing a culture of continuous improvement in surgical care.

Complications

A complication is defined as any deviation from the expected postoperative course, which may impact patient recovery and require additional intervention.(33)

The Clavien-Dindo classification(34) is a widely accepted system for grading surgical complications based on their severity. It categorizes complications on a five-point scale, ranging from minor deviations that require no significant intervention (Grade I) to life-threatening conditions and mortality (Grade V).(35)

Grade	Definition
Grade I	Deviation from normal post-operative course not requiring surgical, endoscopic, or radiological intervention. Includes use of antiemetics, antipyretics, analgesics, diuretics, electrolytes, physiotherapy, and bedside wound care.
Grade II	Complications requiring drug treatments beyond Grade I, such as blood transfusion or total parenteral nutrition (TPN).
Grade III	Complications requiring surgical, endoscopic, or radiological intervention. - Grade IIIa: Intervention without general anesthesia. - Grade IIIb: Intervention under general anesthesia.
Grade IV	Life-threatening complications requiring intensive care, including CNS complications (e.g., brain hemorrhage, ischemic stroke, subarachnoid hemorrhage). Excludes transient ischemic attacks (TIAs). - Grade IVa: Single-organ dysfunction (e.g., dialysis). - Grade IVb: Multi-organ dysfunction.
Grade V	Death of patient.

Step 3: Data Collection

With the rapid advancement of technology and healthcare information systems, traditional paper-based data collection methods for surgical audits have become largely outdated. Modern digital platforms, including web-based audit systems and electronic logbooks, now offer efficient, secure, and scalable alternatives. These tools provide significant advantages such as enhanced data protection to safeguard patient confidentiality, reduced data entry errors through automated input validation, and seamless integration with large-scale datasets for advanced analytics and benchmarking. Additionally, real-time reporting capabilities allow for timely decision-making, making it easier for surgical teams to implement corrective actions and drive quality improvement initiatives.

Maximizing the effectiveness of audit data depends heavily on the accuracy and timeliness of collection. Therefore, it is essential to consider who will be responsible for entering and reviewing the data. One must ask whether the clinician will input the information directly or whether it will be verified before final submission. The credibility of data hinges on accurate diagnosis recording and complication grading, which must be consistently reviewed. Integration with hospital information systems can help streamline the process, but the reliability of such extracted data depends on who initially entered it and the level of oversight in the system.

A structured, well-planned approach to data collection plays a pivotal role in enhancing the overall quality of audits. It supports clearer decision-making, facilitates robust evaluations, and contributes to improved patient outcomes. However, before launching into data collection, several critical considerations must be addressed to ensure the audit delivers meaningful insights. First, the relevance of the data must be assessed—is it aligned with the audit's objectives? If certain metrics, such as high postoperative readmission rates, are identified, the audit scope may need to expand to include elements like discharge planning and post-operative follow-up.

Second, the data's ability to provide valid assessments should be evaluated. For example, when assessing complication rates, it's vital to differentiate between minor complications (such as Grade I events) and severe or life-threatening ones (like Grade IV). This distinction is crucial for accurately measuring compliance with standards.

Additionally, it may be necessary to revisit and revise the existing audit standards themselves. Clinical protocols evolve—if an Enhanced Recovery After Surgery (ERAS) pathway has been introduced, benchmarks regarding hospital stay duration or postoperative mobility may need updating.

Lastly, the audit methodology should be examined for opportunities to improve accuracy, efficiency, and completeness. If inconsistencies in complication grading are observed in hospital records, introducing standardized tools or mandatory verification systems could greatly enhance reliability. A carefully designed data collection strategy that incorporates these considerations helps ensure that audits are both informative and impactful, ultimately contributing to continuous quality improvement in surgical care.

Step 4: Presentation and Analysis

A surgical audit is more than a tool for data collection—it is a mechanism for learning and driving improvements in clinical practice. The ultimate goal should always be to implement changes that lead to better patient outcomes. To achieve this, audit findings must be communicated effectively, and the results must lead to action. One of the most effective strategies for this is the clear and visual presentation of data. Using charts, graphs, and tables helps make trends, patterns, and outliers immediately apparent. Instead of overwhelming the audience with excessive numbers, the focus should be on emphasizing key points that inform decision-making.

Another critical component of interpreting audit results is comparing the findings to established clinical standards. Performance should be assessed against national or institutional benchmarks and guidelines, which allows for the identification of areas requiring improvement. Variations from expected norms should be carefully evaluated to determine whether they reflect substandard care, evolving practices, or the need to update existing standards.

When issues are identified, it is important to understand their root causes. Whether deviations arise from system inefficiencies, technical errors, or individual variations in practice, root cause analysis is necessary. Case reviews and structured team discussions can reveal hidden problems that might not be immediately apparent in the data alone.

Following this, the next step is to develop actionable, practical solutions. Recommendations should be evidence-based, realistic, and achievable within the given resources and context. Creating clear, goal-oriented plans is essential to translating insights into improvements.

Finally, the success of an audit depends on the involvement of key stakeholders. Engaging clinicians, nursing staff, and hospital administrators ensures that changes are supported and implemented effectively. Promoting a culture of continuous learning, regular feedback, and collaborative improvement helps sustain progress and fosters long-term gains in surgical quality and patient safety.

What is Peer Review?(36)

Peer review is a professional evaluation process wherein individuals with comparable training and experience assess each other's work. In the context of surgery, this typically involves fellow surgeons reviewing each other's clinical performance to ensure adherence to best practices and to enhance patient outcomes. Peer review helps uphold clinical standards, improve patient safety, and foster a culture of continuous learning. Participants in peer review are usually surgeons with similar expertise who can provide informed and constructive feedback. However, the process can be further enriched by incorporating multidisciplinary perspectives, including those from surgical trainees, senior nursing staff, and other healthcare professionals who interact closely with surgical teams. Their insights contribute to a more comprehensive evaluation of care delivery.

The primary objectives of peer review are to ensure the quality and safety of surgical practices, identify opportunities for improvement, and facilitate professional development through feedback. To be truly effective, peer review must occur in an environment that emphasizes confidentiality, mutual trust, and collaboration. Rather than being a one-time assessment, peer review should be viewed as an ongoing process that supports the refinement of clinical skills and systems.

Confidentiality is a foundational element of peer review. All patient information and audit data must be handled with discretion to protect patient rights and to ensure surgeons feel safe engaging honestly in the process. The discussions during peer

review meetings should remain strictly professional and focused on quality improvement—not be used for external disciplinary action or litigation.

Trust and professionalism are essential in facilitating open and productive conversations. Review sessions should encourage candid, non-judgmental dialogue aimed at learning from clinical experiences and identifying both strengths and weaknesses. The focus must be on collaborative problem-solving, leading to actionable improvements rather than assigning blame.

It is important to distinguish peer review from educational exercises such as grand rounds and case presentations. While these forums offer valuable learning experiences, they lack the structure, confidentiality, and depth of formal peer review. Grand rounds primarily serve educational purposes, whereas peer review is a targeted, structured evaluation process integral to surgical audits and performance management.

Peer review must also avoid becoming a platform for blame or self-promotion. It should not be used to single out individuals for criticism or to highlight personal accomplishments. Instead, the emphasis should remain on education, risk management, and continuous quality improvement. By keeping the focus on shared learning and clinical advancement, peer review can significantly contribute to better patient care and a more supportive surgical culture.

Types of Surgical Practice and Peer Review

Peer review processes should be adapted to fit the nature of the surgical practice in order to ensure that every surgeon receives meaningful feedback and consistently upholds high clinical standards. There are three main categories of surgical practice that define how peer review should be structured.

The first category includes surgeons working in a unit or group practice, such as those in hospital-based teams, specialist units, or multidisciplinary groups. For these surgeons, peer review should take place at least every six months, though more frequent reviews may be beneficial in some settings. This model encourages collaborative learning and helps maintain standardized care protocols across the team, reinforcing a culture of shared responsibility and continuous improvement.

The second category consists of independent surgeons or heads of single specialist teams who may not work as part of a cohesive surgical unit but still operate within a hospital that includes other surgical specialists. For this group, peer review should be carried out biannually and should include colleagues from the same or closely related specialties. This structure allows for benchmarking and sharing of best practices, even when the day-to-day clinical environment is more individualized.

The third category includes surgeons operating in isolation, such as those who are the only surgical consultant in a hospital or region, and therefore lack direct peers within the same institution. In such cases, peer review may take the form of regional visits, virtual meetings, teleconferencing, or external audits conducted by specialists from other hospitals. Although junior staff such as registrars are not considered true peers to a consultant, they can still provide valuable input during audit meetings and discussions.

By tailoring peer review mechanisms to the specific context in which a surgeon practices, healthcare institutions can promote consistent quality assurance and support professional growth across all levels of surgical care.

Key Features of a Peer Review Meeting

An effective peer review meeting is built on key principles that ensure meaningful engagement, accountability, and continuous quality improvement in surgical practice. First and foremost, all surgeons must be active members of a peer review group consisting of at least three participants. This structure fosters collaboration and diversity of opinion. The environment in which peer reviews are conducted also plays a critical role. Meetings should take place in private, distraction-free settings equipped with appropriate facilities for projecting case data and images. Providing refreshments such as coffee can help participants remain focused and engaged throughout discussions.

The role of the Chairperson is central to maintaining order and fairness. This position should rotate among group members to ensure equitable participation. Alternatively, institutions may appoint an independent chair, such as a medical director or a retired surgeon, to facilitate discussions objectively. Proper scheduling and attendance are

essential—meetings should be planned in advance to maximize participation, and attendance logs must be maintained to monitor consistency and engagement.

In terms of frequency, individual surgeons should undergo peer review at least every six months. Some units may benefit from more frequent reviews, such as monthly or quarterly audits. These regular sessions allow for in-depth trend analysis, which helps identify recurring issues and guides long-term improvements. A thorough review process should encompass both individual case assessments and long-term evaluations, as well as comparative audits, targeted investigations of specific problems, and follow-ups on any recent changes implemented within the department.

Serious clinical events must be reviewed comprehensively, and it is the Chairperson's responsibility to ensure that such cases receive proper attention. Furthermore, peer reviews should focus on detecting system-level deficiencies and recommending actionable solutions. If significant quality or safety concerns are identified, they must be escalated to the hospital's medical or administrative leadership or to the relevant specialty group executive for further evaluation.

Any plans or recommendations resulting from the review should be formally documented at the conclusion of each meeting. A specific individual—such as a hospital administrator, surgical manager, consultant, or registrar—should be appointed to oversee the implementation of these action items. It is equally important to ensure that all assigned actions are followed through within a reasonable timeframe. The final outcomes must be recorded to maintain accountability and serve as reference points for future audits.

Finally, hospitals must provide the necessary support and infrastructure to facilitate effective peer reviews and surgical audits. This includes access to clinical records, data systems, and procedural lists. Since surgical audits are often mandatory for hospital accreditation, institutions are obligated to assist in their execution. Even at a minimum, hospitals should maintain an updated list of surgical procedures to support the audit and review process. With appropriate planning, structure, and institutional support, peer review meetings can significantly enhance clinical governance and improve surgical care standards.

Step 5: Implement Changes and Monitor Progress

Once recommendations from a surgical audit or peer review are finalized, the next step is to ensure their effective implementation within the healthcare system. These changes must be systematically introduced into clinical practice so that the intended improvements can be realized. It is essential to communicate the modifications clearly to all affected staff members, ensuring that everyone involved in patient care is aware of what is changing and why. Providing training sessions, written guidelines, or visual aids can help reinforce the rationale and expected impact of the changes, facilitating smoother adoption and compliance.

Following implementation, the team must monitor the effects of the changes to assess whether they are producing the desired outcomes. Evaluation should focus on improvements in both patient care and clinical workflow to ensure that the recommendations are translating into real, measurable benefits. To support this, it is important to determine an appropriate monitoring strategy. If a continuous total practice audit system is not in place, targeted methods such as periodic reviews, spot audits, or scheduled follow-ups can help track progress and maintain momentum.

In the long term, comparing data across six- to twelve-month periods allows healthcare teams to identify sustained trends and quantify improvement. This analytical approach provides objective evidence of the changes' effectiveness, closing the loop in the audit cycle and reinforcing a culture of accountability and continuous quality improvement.

Settings for Surgical Audit

Surgical audits are conducted across a range of healthcare settings, encompassing both public and private sectors. Although the structure and implementation of audits may vary depending on the environment, the primary goal remains the same: to enhance patient care and surgical outcomes through systematic and continuous evaluation.

In public healthcare settings, most surgical units routinely organize Morbidity and Mortality (M&M) meetings along with detailed reviews of adverse surgical outcomes. These meetings, while serving as a form of audit, are only effective when conducted

with a clear, structured framework. A well-organized audit helps maintain clinical standards, address deviations promptly, and guide meaningful improvements in surgical practice. The widespread use of electronic information systems in public hospitals has significantly improved data collection efficiency. These tools facilitate real-time data integration into the audit process, enabling hospitals and healthcare networks to assess surgical performance consistently, ensure compliance with established standards, and develop strategies to improve overall patient care.

In private practice, surgeons may face greater challenges in accessing structured audit systems and peer review opportunities. When no formal audit system is in place, it is highly recommended that these surgeons engage with specialty or sub-specialty group audits. Participation in a broader professional network supports benchmarking against national standards, promotes constructive peer feedback, and helps identify areas where patient care and clinical practices can be refined. This collaborative approach ensures that high standards are upheld, even outside of institutional environments.

Surgeons in rural or isolated settings, including those working in smaller hospitals, should develop regional or specialty-specific peer connections to support effective surgical audits and performance reviews. When in-person meetings are not practical, video conferencing offers a viable alternative, allowing real-time discussions and review. In areas where video communication is limited due to poor internet access, teleconferencing remains a useful fallback to maintain consistent peer engagement. Additionally, regional or national bodies can conduct anonymous benchmarking exercises, comparing individual or institutional surgical performance across similar practice types. These comparisons must be interpreted with caution and take into account important factors such as differences in case complexity, patient comorbidities, and the size and scope of surgical practices. By addressing these variables, outcome comparisons can offer more accurate insights and serve as a valuable tool for guiding improvements.

Overall, adapting surgical audit strategies to the realities of each clinical setting—be it urban, private, or remote—ensures that all surgeons remain engaged in continuous quality assurance, professional development, and safe, effective patient care.

Importance of Safe Surgery(37)

Surgical care has long been an essential pillar of global healthcare, playing a vital role in the treatment and management of a wide range of medical conditions. As the incidence of traumatic injuries, cancers, and cardiovascular diseases continues to rise worldwide, the significance of surgical intervention within public health systems is expected to grow even further. Surgery is often the only effective intervention for alleviating suffering, reducing long-term disability, and lowering the risk of death in patients affected by such conditions. Every year, millions of individuals undergo surgical procedures, which together contribute to approximately 13% of the global burden of disease measured in disability-adjusted life years (DALYs).

Despite its immense potential to save lives, surgical care is not without risk. When performed without proper safety measures, surgery can result in serious complications, harm, or even death. The widespread nature of surgical interventions amplifies the impact of unsafe practices. Studies have reported that the crude mortality rate following major surgery ranges between 0.5% and 5%, and complications occur in up to 25% of patients undergoing inpatient procedures. In high-income countries, nearly half of all adverse events experienced by hospitalized patients are associated with surgical care, highlighting the significant risks involved. Moreover, it is estimated that at least 50% of surgery-related harm is preventable, indicating a major opportunity for improvement. Alarmingly, in certain low-resource settings such as sub-Saharan Africa, mortality rates associated with general anesthesia can be as high as 1 in 150.

These figures underscore the urgent need for the implementation of robust safety protocols in surgical practice. Enhancing the safety and quality of surgical care is critical not only for reducing preventable harm but also for strengthening overall healthcare delivery systems and improving patient outcomes on a global scale.

Global Efforts to Improve Patient Safety

In 2002, the World Health Assembly (WHA) called for enhanced patient safety, leading to the launch of WHO Patient Safety in 2004. This initiative united global leaders to reduce healthcare-related harm through targeted efforts such as the Global Patient Safety Challenges, advocacy programs like Patients for Patient Safety, and the development of best practice guidelines. The first Global Patient Safety Challenge in 2005–2006 focused on infection prevention, introducing standardized hand hygiene practices and WHO's first Guidelines on Hand Hygiene in Health Care. These efforts aim to improve healthcare safety and save millions of lives worldwide.(38)

The project began in autumn 2006, with an international consultation in January 2007, bringing together global experts. Following this, expert working groups reviewed scientific evidence, drafted guidelines, and collaborated to develop recommendations. A steering group, including project leaders and working group chairs, finalized the guidelines. Nearly 100 international experts contributed to the document, which was pilot tested across six WHO regions to assess feasibility, resource requirements, reliability, and cost-effectiveness before implementation.

Surgical complications have become a leading cause of death and disability worldwide. In 2004, an estimated 187–281 million major surgeries were performed annually—nearly double the number of childbirths (39)—with significantly higher risks. In industrialized nations, major complications occur in 3–22% of inpatient surgeries, with mortality rates between 0.4–0.8%, nearly half of which are preventable (40,41). In developing countries, mortality rates for major surgery range from 5–10% (42–44), with anesthesia-related deaths reaching 1 in 150 in parts of sub-Saharan Africa (45). Postoperative infections and complications remain a global concern, highlighting the need for improved surgical safety measures.

Safe Surgery Saves Lives Approach

The Safe Surgery Saves Lives programme focuses on improving surgical safety and reducing complications through four key strategies:

1. Enhancing Awareness – Providing critical information to clinicians, hospital administrators, and public health officials about the role and impact of surgical safety in public health.
2. Establishing Surveillance Measures – Defining a standardized set of "surgical vital statistics" for national and international monitoring of surgical care.
3. Developing a Universal Safety Checklist – Creating a simple yet effective surgical safety checklist that can be implemented across all healthcare settings to improve patient outcomes.
4. Global Implementation and Testing – Piloting the checklist and surveillance tools in WHO regions before widespread adoption in hospitals worldwide.

At the core of this initiative are the WHO Guidelines for Safe Surgery, which outline essential safety standards. These guidelines were developed by systematically evaluating evidence, assessing their potential impact, and designing measures to monitor their effectiveness.

The programme's surgical safety checklist reinforces best practices across preoperative, intraoperative, and postoperative stages, ensuring critical safety steps are followed efficiently. While some routine adjustments may be required, implementing these standards can lead to significant life-saving improvements in all healthcare environments, from high-resource hospitals to low-income settings.

The WHO Patient Safety Second Global Patient Safety Challenge highlights that every country has the opportunity to enhance surgical care safety, ultimately reducing preventable complications and deaths.

Essential Objectives for Safe Surgery

Surgical care is an inherently complex process that involves a series of coordinated steps tailored to each individual patient. In order to reduce preventable complications and fatalities, operating teams must adhere to a core set of safety principles. The World Health Organization (WHO) Safe Surgery Guidelines outline ten essential safety objectives that surgical teams should follow to ensure optimal patient outcomes and procedural safety.

First and foremost, it is critical to verify the correct patient and correct surgical site before any procedure begins. This simple yet vital step helps avoid wrong-site surgeries. Secondly, teams must ensure safe administration of anesthesia, balancing effective pain management with the minimization of anesthesia-related harm. Anticipating and managing airway and respiratory complications is another key objective, as these are among the most life-threatening events in the operating room.

Blood loss must be carefully anticipated and managed, especially in high-risk cases, and all known allergens and contraindicated medications should be avoided to prevent allergic or adverse reactions. Strict infection control measures should be in place to minimize surgical site infections, and all instruments and sponges must be meticulously accounted for to prevent retained surgical items in the patient.

Additionally, surgical specimens must be handled with care, accurately labeled to ensure correct identification and diagnosis. Clear and effective communication among all team members is essential for coordinating care and ensuring that vital information is conveyed at every step of the procedure. Finally, healthcare institutions should implement robust systems for the monitoring and surveillance of surgical activity, including capacity, procedural volume, and patient outcomes.

By consistently applying these ten objectives, surgical teams can dramatically improve both patient safety and the quality of surgical care delivered. These principles form the foundation of safer surgery and contribute to better long-term health outcomes.

Organization of the WHO Surgical Safety Guidelines

The WHO Surgical Safety Guidelines are meticulously structured to enhance patient safety and minimize the risks associated with surgical procedures. The guidelines begin by identifying essential safety objectives for surgical care. These objectives are supported by a thorough evaluation of clinical evidence and professional experience to determine the most effective and practical approaches for achieving them.

The recommended practices outlined in the guidelines are classified into three distinct categories based on their proven impact on reducing surgical harm and their feasibility of implementation. The first category, "Highly Recommended," includes essential safety measures that are expected to be applied in every surgical case, regardless of setting. The second category, "Recommended," comprises practices that contribute to safer outcomes and are encouraged, although their applicability may depend on specific clinical or institutional contexts. Finally, "Suggested" practices are considered optional but potentially beneficial depending on the nature of the surgery or the operating environment.

To facilitate practical use of these guidelines in daily surgical workflows, the WHO has integrated the most vital "highly recommended" practices into two key tools. The WHO Safe Surgery Checklist provides a structured method to reinforce safety measures at key moments—before induction of anesthesia, before skin incision, and before the patient leaves the operating room. The Surgical Vital Statistics tool offers a set of indicators to track surgical performance and outcomes, supporting data-driven improvement efforts.

These guidelines have undergone international pilot testing and final expert review. As part of its broader mission, WHO Patient Safety aims to promote a global culture of surgical safety, reduce preventable complications, and ultimately save lives through evidence-based and universally applicable strategies.

Objective 1: Ensuring Surgery is Performed on the Correct Patient and Site

To prevent serious errors such as wrong-patient or wrong-site surgeries, surgical teams must adhere to strict and standardized verification protocols. The World Health Organization (WHO) outlines a series of highly recommended practices to ensure patient safety during the perioperative period.

First, patient identification is critical. Before the administration of anesthesia, a designated team member should confirm the patient's identity using at least two reliable identifiers, such as the patient's full name and date of birth. This should be verified both verbally and by checking physical documentation, such as an identity bracelet.

Next, informed consent and procedural verification must be conducted. A team member should confirm that the patient has provided informed consent and validate the intended procedure and site of operation by speaking directly with the patient, whenever possible. This step ensures that all parties agree on what surgery is being performed and where.

In surgeries involving laterality or multiple anatomical structures, such as procedures on fingers or vertebrae, the operating surgeon must clearly mark the surgical site. This marking should be permanent and unambiguous, verified again by both the anesthetist and the nurse. Marks like an "X" should be avoided due to potential misinterpretation.

Finally, the surgical team should perform a final verification or "time-out" immediately before the incision. During this pause, the surgeon should verbally confirm the patient's name, the planned procedure, and the surgical site, while the anesthetist and nurse cross-check the details to ensure total agreement.

Objective 2: Ensuring Safe Administration of Anesthesia

To minimize the risks associated with anesthesia, surgical teams must strictly adhere to essential monitoring and safety protocols. These guidelines help prevent complications, improve patient outcomes, and ensure the safe administration of anesthesia throughout the surgical procedure.

It is highly recommended that anesthesia is continuously supervised by a professionally trained provider. This individual must remain present for the entire duration of the procedure. In exceptional emergencies where temporary absence is unavoidable, responsibility should be carefully delegated using sound clinical judgment.

Ensuring proper oxygenation and ventilation is paramount. All patients undergoing general anesthesia must receive supplemental oxygen. Tissue oxygenation and perfusion should be continuously monitored using a pulse oximeter that features an audible, variable-pitch tone. The airway must be closely observed and assessed, both visually and via auscultation, and mechanical ventilation systems must include a disconnect alarm to promptly alert the team of any disconnection.

Circulatory monitoring should also be continuous. Techniques such as auscultation, palpation, and electronic cardiac monitoring are used to assess circulation. Blood pressure should be recorded at intervals no longer than five minutes, and more frequently if the patient's condition demands it. For longer or more complex procedures, temperature monitoring and evaluation of anesthesia depth through clinical observation are also important to maintain patient stability.

Among the recommended practices, monitoring inspired oxygen concentration is crucial. Equipment should include alarms for both low oxygen levels and total oxygen supply failure. Systems designed to prevent the delivery of hypoxic gas mixtures are strongly advised. Capnography—the measurement of expired carbon dioxide—is essential for confirming correct endotracheal tube placement and assessing ventilation adequacy. Monitoring volatile agent concentrations, inspiratory and expiratory gas volumes, and maintaining accurate gas exchange information further enhances safety.

Cardiac monitoring should include electrocardiography to observe heart rate and rhythm, and a defibrillator should be readily available. In cases where temperature fluctuations are expected, body temperature must be continuously tracked. When neuromuscular blocking agents are used, a peripheral nerve stimulator should be employed to assess the depth of paralysis and guide appropriate dosing.

Objective 3: Managing Airway and Respiratory Risks in Surgery

To improve patient safety during surgery, it is essential for the surgical and anesthesia teams to proactively anticipate and effectively manage any potential airway or respiratory complications. Several highly recommended practices have been established to ensure optimal outcomes.

Every patient should undergo a structured airway assessment prior to the induction of anesthesia, regardless of whether intubation is anticipated. This preliminary evaluation helps anesthetists identify any potential challenges and formulate an appropriate airway management plan. In situations where a difficult airway is suspected, provisions must be in place for immediate assistance, and a backup strategy should be prepared in advance.

For patients with a known history of airway difficulties, anesthetists should consider alternative techniques such as regional anesthesia or awake intubation using local anesthetic agents. These strategies can help avoid complications associated with conventional airway management. Additionally, anesthesia providers should continuously refine their skills in airway management and maintain proficiency in various techniques to adapt to different clinical scenarios.

After intubation, the correct placement of the endotracheal tube must be confirmed through multiple methods, including auscultation of breath sounds, monitoring for gastric insufflation, and pulse oximetry. Furthermore, patients scheduled for elective surgery should follow preoperative fasting protocols, and those identified as being at risk of aspiration should receive pre-treatment to reduce gastric acidity and volume.

Among the recommended practices, capnography should be used immediately following intubation to confirm the correct placement of the endotracheal tube and monitor ventilation. Proper documentation of the airway assessment and intubation experience—including whether the process was routine or difficult—should be recorded in the anesthesia report for future reference and to guide future interventions.

Together, these measures create a safer surgical environment, minimizing the risk of airway-related complications and enhancing overall patient safety throughout the perioperative period.

Objective 4: Managing the Risk of High Blood Loss in Surgery

To ensure patient safety, surgical teams must proactively anticipate and prepare for the possibility of significant blood loss during surgical procedures. This begins with a preoperative assessment by the anesthetist, who should evaluate the likelihood of high-volume blood loss prior to the induction of anesthesia. If the risk is not immediately evident, it is essential for the anesthetist to consult with the surgical team to determine whether the planned operation carries a potential for substantial bleeding. Open communication at this stage can help guide appropriate preparation and intervention.

Before making the first incision, the surgical team should conduct a final evaluation of bleeding risk. If the risk is deemed substantial, the team must confirm that the patient has secure and adequate intravenous access to allow for rapid fluid and blood product administration if needed.

As a recommended safety measure, a designated team member should verify the availability of required blood products before the procedure begins. Confirming this resource availability in advance is critical to preventing delays and ensuring timely treatment in the event of major hemorrhage.

Objective 5: Preventing Allergic and Adverse Drug Reactions

To reduce the risk of allergic reactions and adverse drug events in the surgical setting, it is essential for surgical teams to enforce strict medication safety protocols. These guidelines ensure accuracy, minimize human error, and protect patients from potentially life-threatening complications related to medication use during surgery.

Among the highly recommended measures, anesthetists must possess a thorough understanding of the pharmacological properties and toxicity risks of every medication they administer. Before giving any drug, the patient's identity must be clearly verified, typically using two identifiers such as name and date of birth. In addition, a complete drug history must be obtained, including any known allergies or previous hypersensitivity reactions. This step is crucial in preventing avoidable complications.

All medications must be clearly labeled, verified, and rechecked before administration, especially when transferred into a syringe. Mislabeling or overlooking verification can lead to dangerous errors. When one healthcare provider administers a drug on behalf of another, explicit communication is vital to confirm the medication's purpose, proper dosage, contraindications, and any additional important information.

Recommended practices further strengthen medication safety. Drug storage areas should be organized methodically, maintaining cleanliness and separating high-risk or look-alike medications to reduce the chance of confusion. Labels on ampoules and syringes must be clear and standardized, with visible information about the drug concentration and expiration date. When medications have similar packaging, steps should be taken to distinguish them to avoid mix-ups.

Any errors related to intravenous drug administration during anesthesia should be promptly documented and subjected to review to improve future practice. Anesthetists are also encouraged to personally prepare and label all medications they administer, further minimizing the risk of miscommunication or misidentification.

By rigorously applying these medication safety protocols, surgical teams can significantly mitigate drug-related risks and enhance overall patient safety in the perioperative environment.

Objective 6: Minimizing Surgical Site Infections

Preventing surgical site infections (SSIs) is a vital aspect of delivering safe and high-quality surgical care. Implementing a series of evidence-based infection control practices throughout the perioperative period can significantly reduce the risk of SSIs and improve overall patient outcomes.

Among the highly recommended measures, the proper use of prophylactic antibiotics is essential. Antibiotics should be routinely administered in clean-contaminated surgeries and considered for clean cases. They must be given within one hour before the skin incision, with careful attention to correct dosage and antimicrobial coverage. In particular, vancomycin infusions should be completed within this pre-incision timeframe. Redosing may be necessary for surgeries that last over four hours or involve excessive blood loss; however, vancomycin typically does not require

redosing if the procedure is under ten hours. Prophylactic antibiotics should be discontinued within 24 hours after surgery to minimize resistance and side effects.

Sterilization of surgical instruments and materials is another crucial element. All equipment must undergo a validated sterilization process, and sterility indicators should be used. Sterility must be confirmed before instruments enter the sterile field and before anesthesia induction, with any breaches promptly reported to the team.

Infection prevention efforts should begin preoperatively. Hair removal should be avoided unless necessary and, if required, should be done by clipping no more than two hours before surgery—shaving is discouraged due to increased infection risk. Intraoperatively, maintaining core body temperature and oxygenation, preparing the surgical site with an effective antiseptic, and ensuring surgical hand antisepsis through proper scrubbing or alcohol-based solutions are essential steps. The surgical team must wear sterile gowns, gloves, and head coverings throughout the procedure.

Several recommended practices further enhance infection prevention. These include discouraging "on-call" antibiotic orders to ensure timely administration, avoiding depilatory creams for hair removal, and advising patients to stop smoking at least 30 days before elective surgery. Patients should also bathe with antiseptic soap before surgery, and any existing infections should be treated in advance. Surgical teams should wear masks throughout the operation and use fluid-resistant drapes. After surgery, the wound should be covered with a sterile dressing for 24–48 hours.

Finally, active surveillance of SSIs by trained infection control staff is essential. Infection rates should be regularly reported to surgeons and hospital administrators to support data-driven improvements. By consistently applying these practices, surgical teams can significantly reduce SSI rates and foster safer surgical environments.

Objective 7: Preventing Inadvertent Retention of Instruments and Sponges in Surgical Wounds

The unintended retention of surgical items (RSIs) such as sponges, needles, sharps, and instruments is a serious and preventable patient safety concern. If left undetected, retained items can lead to severe complications, additional surgeries, infections, and

even mortality. To minimize this risk, surgical teams must implement standardized counting and verification procedures at every stage of surgery.

One of the most highly recommended practices is to establish comprehensive counting protocols. A complete count of all sponges, sharps, needles, instruments, and any other potentially retainable items must be performed when entering critical body cavities, including the peritoneal, retroperitoneal, pelvic, or thoracic spaces. These counts must be conducted at least twice—once at the beginning of the procedure and once before closure. To ensure accuracy, the count should always be performed by two trained team members, including a scrub nurse or surgical technologist, with each count cross-verified.

Before any anatomical cavity or wound is closed, the surgeon is responsible for conducting a thorough visual and manual exploration of the surgical field to confirm that no foreign objects remain inside. If a discrepancy in the count is identified, the team must immediately halt wound closure until the missing item is located and resolved through a complete search.

Clear and accurate documentation of the counting process is also critical. The names and roles of the individuals performing the count should be recorded, and the final results must be explicitly communicated to the surgeon. A shared understanding of the final count ensures accountability and reinforces a safety-first culture in the operating room.

By adhering to these practices, surgical teams can dramatically reduce the risk of retained surgical items, thereby improving patient safety, minimizing complications, and supporting better surgical outcomes.

Objective 8: Securing and Accurately Identifying All Surgical Specimens

Proper handling and identification of surgical specimens is vital for ensuring accurate diagnoses and safe, effective patient care. Mislabeling or misidentification of specimens can lead to diagnostic errors, delayed treatment, and serious consequences for patient outcomes. To avoid such errors, surgical teams must implement strict labeling protocols during every procedure.

Among the highly recommended measures, all surgical specimens must be clearly and accurately labeled with the patient's full identity, the type of specimen, and the exact anatomical site and laterality from which it was collected. To ensure accuracy, the labeling process should involve two team members: one team member reads the specimen label aloud while another verbally confirms that the details match the patient's information and the surgical field.

This double-check system significantly reduces labeling errors and supports the safe handling of all pathological materials.

Objective 9: Effective Communication and Exchange of Critical Information for Safe Surgery

Effective communication and documentation among surgical team members is vital for ensuring patient safety and achieving successful surgical outcomes. Structured, clear, and timely information exchange helps reduce preventable errors, supports informed decision-making, and ensures continuity of care throughout the perioperative period.

Among the highly recommended measures, a thorough preoperative briefing should take place before the skin incision. The surgeon must clearly outline the critical steps of the procedure to the entire team, including nurses, anesthetists, and surgical assistants. This includes highlighting any anticipated complications, such as the potential for significant blood loss, and identifying any specialized equipment required—such as intraoperative imaging tools, specific instruments, or implants. Simultaneously, the nursing team should communicate any concerns related to safety or unavailable equipment, while the anesthetist must inform the team of anesthesia-related risks or anticipated resuscitation challenges.

In surgeries involving multiple anatomical parts—such as bilateral limbs, spinal levels, or multiple digits—or where intraoperative imaging is necessary to guide resection, it is essential to confirm that relevant imaging is available and properly displayed. This ensures correct surgical site identification and supports decision-making during the procedure.

Following the procedure, a structured postoperative handover should occur before the patient exits the operating room. The surgeon must brief the team on any deviations from the original plan, note potential postoperative complications, and communicate key aspects of postoperative care, such as antibiotic use, thromboembolism prophylaxis, dietary restrictions, and drain care. The anesthetist should summarize the patient's intraoperative condition and outline any recovery needs, while the nursing team must report any intraoperative concerns or observations.

Maintaining accurate and complete surgical records is equally important. All surgical documentation should be legible, objective, contemporary, tamper-proof, and written in original ink. Each page of documentation must include the patient's full name and hospital identification number. All entries should be promptly recorded, signed, dated, and timed. Any corrections must be clearly marked, signed, dated, and explained to maintain transparency and legal integrity.

Each discipline within the surgical team holds responsibility for specific records:

- The surgeon's record must detail the primary and secondary procedures performed, list all assistants, note procedural steps, and estimate intraoperative blood loss.
- The anesthetist's record should include continuous monitoring of vital signs, medications and fluids administered, and any episodes of intraoperative instability.
- The nursing record must document counts of sponges, needles, sharps, and instruments, list the personnel involved, and outline actions taken in case of count discrepancies.

By adhering to these communication protocols and documentation standards, surgical teams can significantly enhance patient safety, reduce errors, and ensure high-quality, coordinated postoperative care.

Objective 10: Establishing Routine Surveillance of Surgical Capacity, Volume, and Outcomes

Routine surgical data collection and surveillance are critical tools for improving patient safety, surgical quality, and health system performance at national, hospital, and individual practitioner levels. By establishing structured monitoring systems, healthcare authorities and facilities can identify trends, benchmark outcomes, and implement targeted quality improvement strategies.

Among the highly recommended measures, the World Health Organization (WHO) encourages all Member States to collect standardized national-level surgical surveillance data. Key indicators should include surgical infrastructure, such as the number of operating rooms available; surgical volume, defined by the number of procedures performed in those operating rooms; and workforce capacity, which involves tracking the number of trained surgeons and anesthetists. In terms of patient outcomes, two essential mortality indicators should be monitored: the day-of-surgery mortality rate and the postoperative in-hospital mortality rate.

At the hospital and practitioner levels, similar metrics should be recorded, including both mortality indicators. These data points offer valuable insight into local practices and performance, enabling healthcare teams to refine care protocols and enhance safety standards.

For countries with more advanced data infrastructure, recommended extended surveillance should be adopted to capture deeper insights. This includes facility classification, distinguishing between hospital and ambulatory settings, as well as between public and private institutions. In terms of workforce specialization, data should reflect the number of trained surgeons by specialty (e.g., general surgery, gynecology, orthopedics, neurosurgery, ophthalmology, otorhinolaryngology, and urology), the presence of surgical trainees or unaccredited practitioners, and the number of trained anesthetists, classified by level (e.g., physician anesthesiologists, nurse anesthetists, anesthesia officers), along with the number of perioperative nurses.

Additionally, surgical volume by procedure should be recorded, focusing on the ten most frequent procedures performed nationally. This includes both elective and emergency surgeries. Mortality outcomes should be disaggregated by procedure type, reporting the proportion of day-of-surgery and in-hospital postoperative deaths associated with each of these high-frequency procedures.

At the hospital and practitioner levels, more detailed surveillance should also include tracking the surgical site infection (SSI) rate, a vital indicator of sterile technique and postoperative care quality. Facilities should also consider using the Surgical Apgar Score, a standardized tool that evaluates patient condition and surgical performance based on blood loss, heart rate, and blood pressure during surgery.

By implementing and routinely analyzing these surveillance measures, healthcare systems can improve accountability, identify systemic gaps, and foster safer, more efficient surgical care across all levels of service delivery.

Surgical Safety Checklist

World Health Organization | Patient Safety
A World Alliance for Safer Health Care

Before induction of anaesthesia

(with at least nurse and anaesthetist)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

Before skin incision

(with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Before patient leaves operating room

(with nurse, anaesthetist and surgeon)

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

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This section outlines a clear and practical guide for implementing the WHO Surgical Safety Checklist, a vital tool for reducing preventable errors and enhancing patient safety in the operating room. Central to its effectiveness is the assignment of a dedicated Checklist coordinator, typically a circulating nurse or another trained clinician. This individual is responsible for leading the team through each phase of the checklist and ensuring that all critical safety steps are completed.

The Checklist is structured into three distinct phases, each aligned with specific moments in the surgical workflow. The first phase, "Before Anaesthesia Induction," involves confirming the patient's identity, verifying the planned procedure, checking that informed consent has been obtained, and assessing risks such as potential blood loss, airway difficulties, or known allergies.

The second phase, "Before Skin Incision," is a moment for the full surgical team to pause and engage in a team briefing. During this step, the team introduces themselves by name and role, confirms the procedure and surgical site, and discusses any anticipated surgical or anaesthetic challenges. It also includes ensuring that prophylactic antibiotics have been administered and that any essential imaging is present and visible.

The final phase, "Before Patient Transfer," occurs at the conclusion of the procedure. The team reviews what surgery was performed, confirms that sponge and instrument counts are correct, verifies that any specimens are properly labeled, and identifies any issues with equipment. This phase also includes a discussion of postoperative care plans and any concerns prior to transferring the patient out of the operating room.

Having a designated Checklist coordinator ensures these crucial steps are not overlooked amid the fast pace of surgery. However, the person selected must possess the interpersonal skills to maintain team cohesion and avoid conflicts. When properly integrated, the Checklist strengthens team communication and promotes a culture of safety without hindering efficiency.

How to Run the WHO Surgical Safety Checklist (In Brief)

The WHO Surgical Safety Checklist is a structured tool designed to improve patient safety in the operating room. To effectively implement the Checklist, a designated Checklist Coordinator must be assigned to oversee its execution. This individual, often a circulating nurse but potentially any clinician involved in the surgery, is responsible for ensuring that each step is completed at the appropriate time.

The Checklist is divided into three key phases, each aligned with specific moments in the surgical process:

1. Before Induction of Anaesthesia
2. Before Skin Incision
3. Before the Patient Leaves the Operating Room

For each phase, the Checklist Coordinator must confirm that the necessary tasks are completed before the surgical team proceeds to the next step. Over time, as the team becomes accustomed to the process, Checklist steps can be smoothly integrated into normal workflow without disrupting efficiency.

Phase 1: Before Induction of Anaesthesia

During the first phase of the WHO Surgical Safety Checklist—before the induction of anaesthesia—the Checklist Coordinator conducts a verbal review with the anaesthetist and, whenever feasible, the patient. This process involves a series of critical safety verifications to ensure readiness and reduce the likelihood of preventable complications. The patient's identity, the intended procedure, and the surgical site must be clearly confirmed against hospital records to eliminate the risk of wrong-patient or wrong-site surgery. If the nature of the surgery requires it, the operative site should be visibly marked in advance. Additionally, the team must confirm that the patient has provided valid, documented informed consent for the procedure. A focused anaesthesia risk assessment is then performed by the anaesthetist, which includes evaluating the potential for significant blood loss—prompting preparations for transfusion if needed—identifying the possibility of a difficult airway, and ensuring that all known allergies are reviewed prior to medication administration. The

anaesthetist must also confirm that the anaesthesia machine and all medications have been checked and are ready for safe use. While it is not mandatory, the presence of the surgeon during this phase is encouraged, as they may offer valuable insight into expected surgical risks and contribute to more comprehensive preparation.

Phase 2: Before Skin Incision

Once the patient is anaesthetized and prepared for surgery, the surgical team pauses for a pre-incision time-out, a critical step designed to confirm key safety elements and ensure complete alignment among team members before the operation begins. During this phase, each member of the surgical team introduces themselves by name and role; if the team has already worked together earlier in the day, a brief confirmation of roles is sufficient. The team then collectively verifies that they are operating on the correct patient, performing the correct procedure, and working on the correct surgical site, including the appropriate side of the body and anatomical location. This is followed by a discussion of the key steps of the surgery, where each team member verbalizes their responsibilities, the expected duration of the procedure, potential challenges or complications, any special equipment or implants that may be needed, and any specific patient-related concerns such as pre-existing conditions that could influence the surgical outcome. The team also confirms that prophylactic antibiotics have been administered within the past 60 minutes if required. Additionally, if radiographic imaging is essential for the surgery, the team ensures that all necessary images are available and correctly displayed in the operating room. This pre-incision checklist phase plays a vital role in preventing wrong-patient, wrong-site, and wrong-procedure events, while also preparing the team to manage any anticipated complications.

Phase 3: Before the Patient Leaves the Operating Room

Before the patient is moved out of the operating room, the surgical team performs a final sign-out review to ensure that all critical safety steps have been completed. The surgeon begins by summarizing the procedure performed, noting any unexpected findings or deviations from the original surgical plan. Simultaneously, the scrub nurse confirms that all surgical instruments, needles, sharps, sponges, and gauze are accounted for, helping to eliminate the risk of retained foreign objects. If biopsy or

tissue specimens were collected during the operation, the team verifies that each specimen is correctly labeled with the patient's identifying information and that it has been properly documented in hospital records. Any equipment malfunctions or technical issues encountered during surgery are also reported and recorded to support maintenance, prevent future failures, and improve workflow. The team then collaboratively reviews the postoperative care plan, discussing key elements such as pain management strategies, medication administration, and venous thromboembolism (VTE) prophylaxis to prevent blood clots. They also confirm instructions for wound care, dressing protocols, and any necessary postoperative monitoring, including whether the patient will require transfer to an intensive care unit. This comprehensive step ensures a smooth and safe transition from surgery to postoperative recovery, reducing complications and supporting continuity of care.

The Role of the Checklist Coordinator

The effectiveness of the WHO Surgical Safety Checklist relies heavily on having a single designated individual, known as the Checklist Coordinator, who leads the process. This person plays a pivotal role in ensuring that each safety step is not only followed but clearly verbalized and completed before the surgical team proceeds to the next stage. The presence of a coordinator helps prevent the omission of critical safety checks and promotes a culture of open communication and teamwork among surgical staff. However, assigning someone to this role requires careful judgment. There may be instances where the Checklist Coordinator encounters resistance from team members, particularly if they need to delay workflow to ensure compliance with checklist protocols. For this reason, hospitals are encouraged to select a respected and assertive team member who can manage the role confidently and diplomatically.

Although the circulating nurse is often appointed as the Checklist Coordinator due to their position and workflow in the operating room, any trained clinician with appropriate knowledge and leadership skills can perform this function. As teams gain familiarity with the Checklist and its purpose, it should eventually become seamlessly embedded into routine surgical practice, enhancing safety without disrupting efficiency.

MATERIALS AND METHODS

MATERIALS AND METHODS

Study place: Department of General Surgery, Santosh Medical College and Hospital, Ghaziabad, Uttar Pradesh.

Duration of Study: 12 Months (April 2024 to April 2025)

Study Design: Hospital based observational study

Study population: Patients admitted preoperatively for elective surgury under Department of General Surgery, Santosh Medical College and Hospital, Ghaziabad

Sample Size: 433

Sample size is calculated using the formula

$$n = deff \times \frac{N\hat{p}\hat{q}}{\frac{d^2}{1.96^2}(N-1) + \hat{p}\hat{q}}$$

The notations for the formulae are:

n = sample size
$deff$ = design effect
N = population size
$\hat{p}$ = the estimated proportion
$\hat{q} = 1 - \hat{p}$
d = desired absolute precision or absolute level of precision

STATISTICAL ANALYSIS & DATA MANAGEMENT

- The data will be collected and entered in MS Excel 2010. Different statistical analysis will be performed using Stata MP-17.
- The one-sample Kolmogorov – Smirnov test will be employed to determine whether the data sets differed from a normal distribution or not. Normally distributed data will be analysed using parametric tests and non–normally distributed data will be analysed using non-parametric tests. Descriptive statistics will be calculated for qualitative and categorical variables. Graphical representation of the variable will be shown to understand the results clearly and to measure the association for categorical dataset will be analysed using Chi-Square test. Independent T-test or student t-test will be applied to measure the mean difference between two groups. Correlation will be estimated to measure the strength of relationship between two or more quantitative variables.
- If p value <0.05, considered as statistically significant and if p-value>0.05, then it is statistically insignificant.

Inclusion Criteria:

- All patients undergoing any major operative procedure in the operation theatre under the Dept. of Surgery.
- All patients undergoing any major operative in the operation theatre under the Dept. of Surgery which experienced any post op complication particularly SSI or mortality.

Exclusion Criteria:

- Emergency surgeries

METHODOLOGY:

This hospital-based observational study was conducted in the Department of General Surgery at Santosh Medical College and Hospital, Ghaziabad, with the aim of assessing the implementation and adherence to the World Health Organization (WHO) Surgical Safety Checklist and evaluating its association with postoperative outcomes, particularly surgical site infections (SSIs) and mortality. The study was carried out over a period of one year, from April 2024 to April 2025, and was designed to include a broad spectrum of surgical patients undergoing major operative procedures under the General Surgery department. A total of 433 patients were included in the study through a process of random sampling.

Patients eligible for inclusion were those undergoing any major elective surgical procedures performed under regional or general anesthesia in the main operation theatre complex of the department. The selection was made without bias to age or gender, provided that the case was conducted under standard operative settings with adherence to the WHO Surgical Safety Checklist. Emergency procedures and minor surgeries—such as those done under local anesthesia, bedside procedures, and short day-care interventions—were excluded from the study to maintain uniformity in perioperative protocol and follow-up expectations.

Preoperative data collection involved systematic documentation of each patient's Unique Hospital Identification (UHID) number, full name, age, gender, relevant medical and surgical history, clinical examination findings, and results of any radiological or laboratory investigations performed prior to surgery. Each patient underwent a comprehensive surgical evaluation as per institutional protocol. The surgical safety checklist, as endorsed by the WHO, was implemented uniformly throughout the study period across all three operative phases—Sign In (before induction of anesthesia), Time Out (before skin incision), and Sign Out (before the patient leaves the operating room). The checklist covered critical points such as patient identification, surgical site and procedure confirmation, anesthesia safety check, airway and blood loss risk assessment, availability of necessary equipment and imaging, and proper communication among surgical team members.

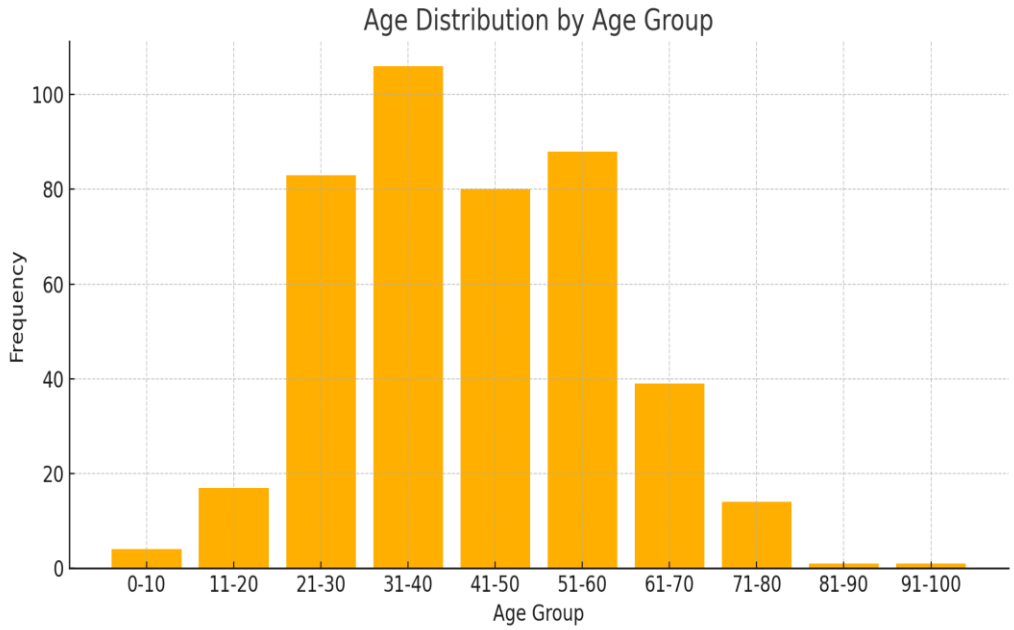
Intraoperative data included details about the type of surgery performed, the type and duration of anesthesia, estimated blood loss, and any intraoperative complications or protocol deviations. All persons involved in the surgical process were trained in advance to ensure consistent application and documentation of the checklist. Following surgery, each patient was monitored during their inpatient stay for the development of any complications. Daily clinical assessments were performed to evaluate wound condition, presence of discharge, and other signs of surgical site infection or deterioration. Mortality was also recorded when applicable, along with cause and time of death, if it occurred during the postoperative hospital stay.

RESULTS

RESULT

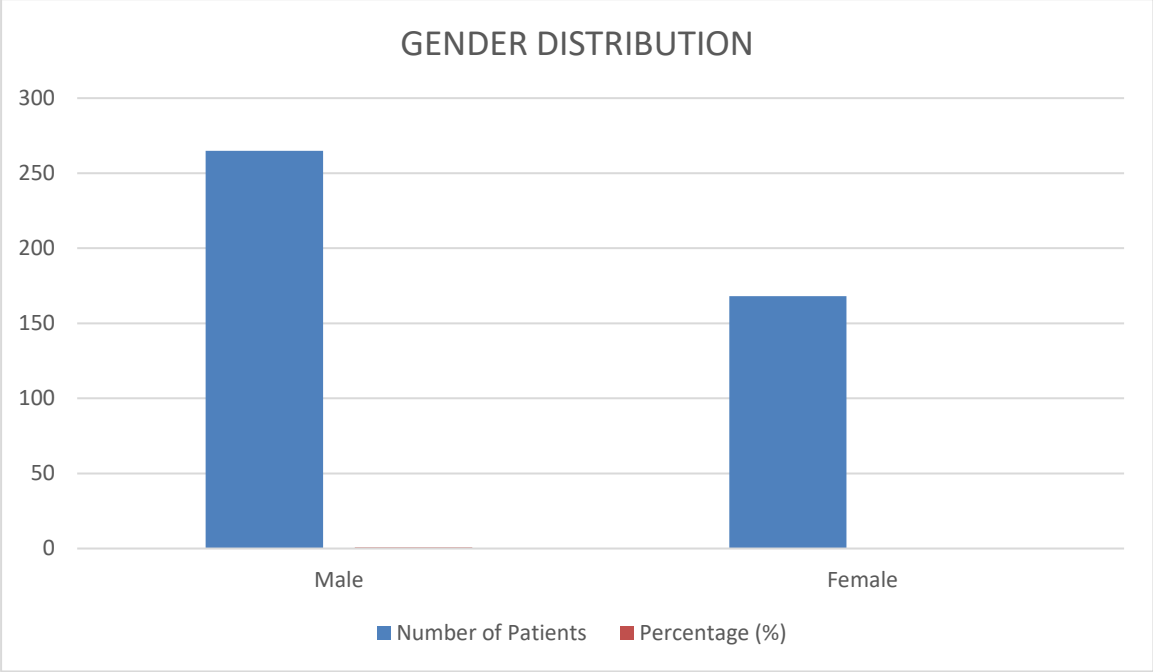
1. AGE DISTRIBUTION

Age Group	Frequency	Percentage (%)
0-10	4	0.92
10-20	17	3.93
21-30	83	19.17
31-40	108	24.94
41-50	80	18.48
51-60	90	20.79
61-70	39	9.01
71-80	14	3.23
81-90	1	0.23
91-100	1	0.23



In this study of 433 patients, the most common age group was **41–50 years**, followed closely by **51–60 years**, indicating a concentration of individuals in the middle-aged demographic.

2. GENDER DISTRIBUTION



Gender	Number of Patients	Percentage (%)
Male	265	65.2%
Female	168	38.8%
Total	**433**	**100%**

In this study data of 433 patients, 65.2% are male (265 individuals) and 38.8% are female (168 individuals).

3. DISTRIBUTION OF SURGICAL PROCEDURES

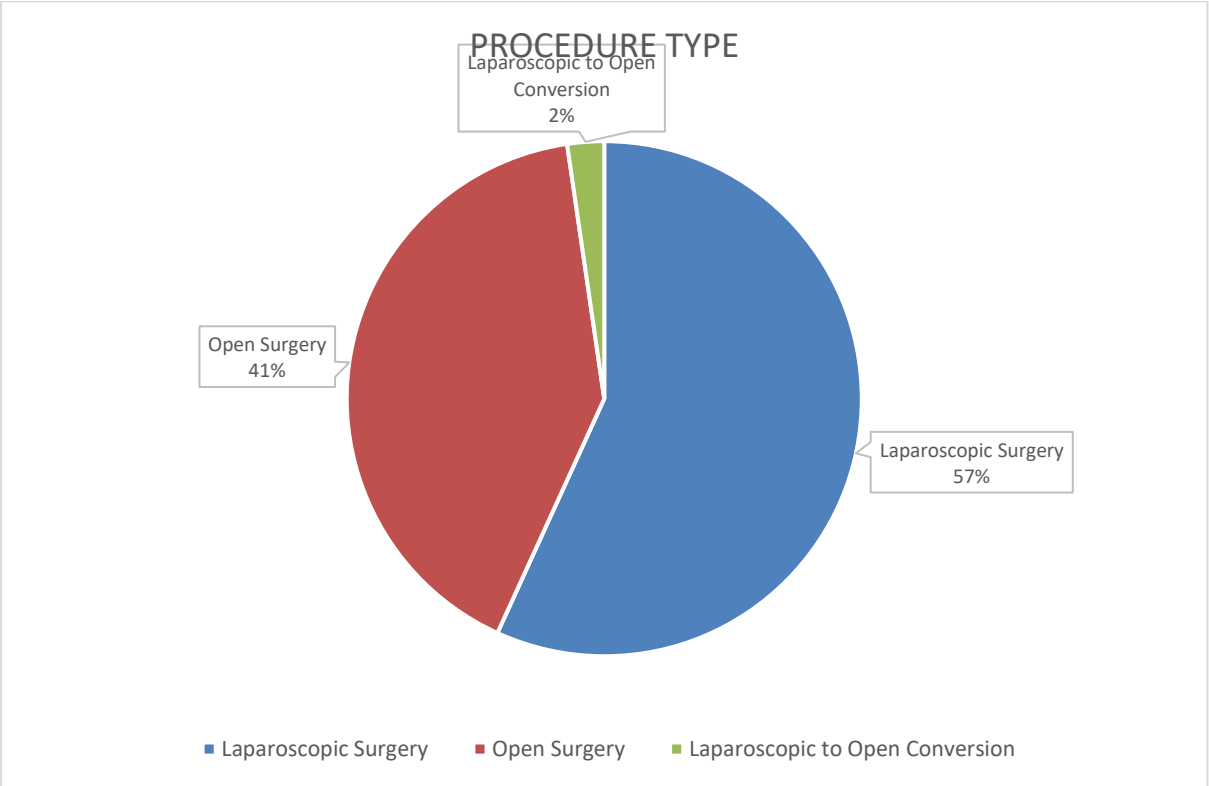
A total of 433 patients underwent surgical procedures, categorized as follows:

Laparoscopic Surgery: Performed in 246 patients (56.8%).

Open Surgery: Conducted in 177 patients (40.9%).

Laparoscopic to Open Conversion: Occurred in 10 patients (2.3%).

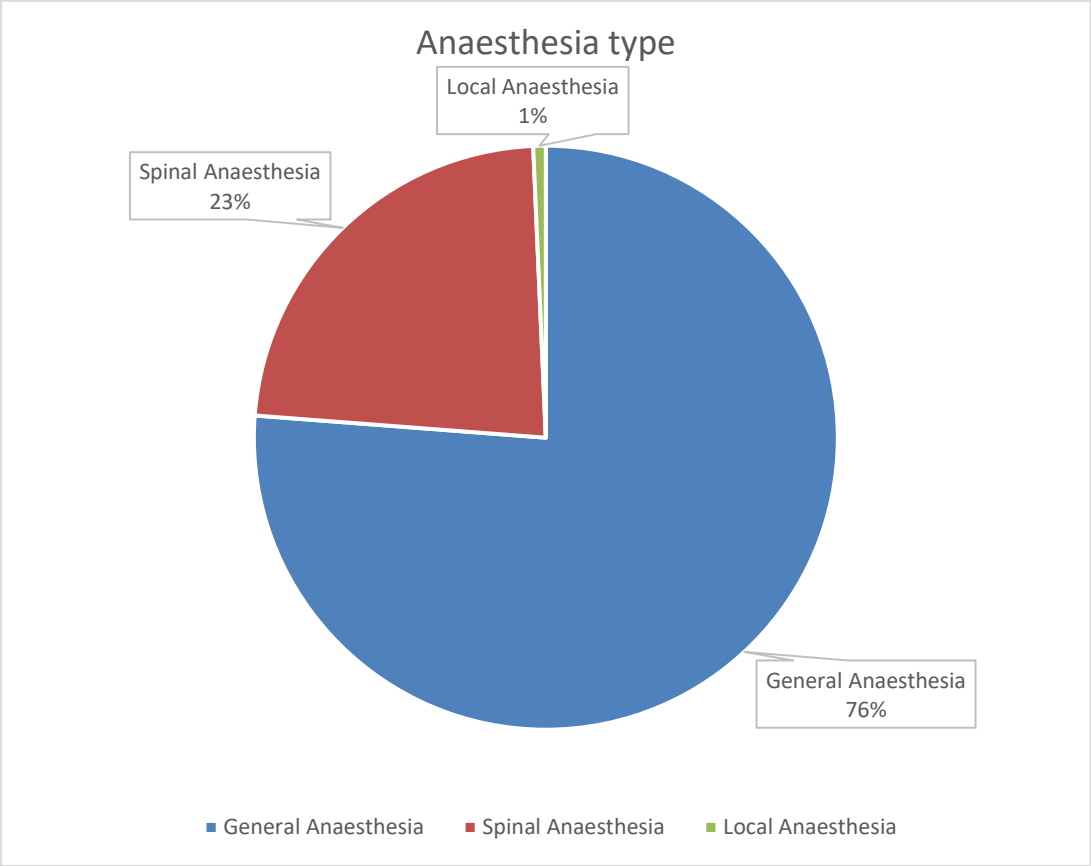
Procedure Type	Number of Patients	Percentage (%)
Laparoscopic Surgery	**246**	**56.8**
Open Surgery	**177**	**40.9**
Laparoscopic to Open Conversion	**10**	**2.3**



4. Anaesthesia Type

In this study, out of 433 patients, 330 were administered General Anaesthesia, 3 under local anaesthesia and 100 were given spinal anaesthesia.

Anaesthesia type	Frequency
General Anaesthesia	330
Spinal Anaesthesia	100
Local Anaesthesia	3



5. INFORMED CONSENT, IDENTITY, SITE AND PROCEDURE VERIFICATION

A total of 433 patients underwent surgical procedures. For all patients, the identity, surgical site, procedure, and consent were verified prior to surgery, ensuring adherence to safety protocols.

Consent Compliance:

100% (433/433) of patients had documented informed consent before surgery.

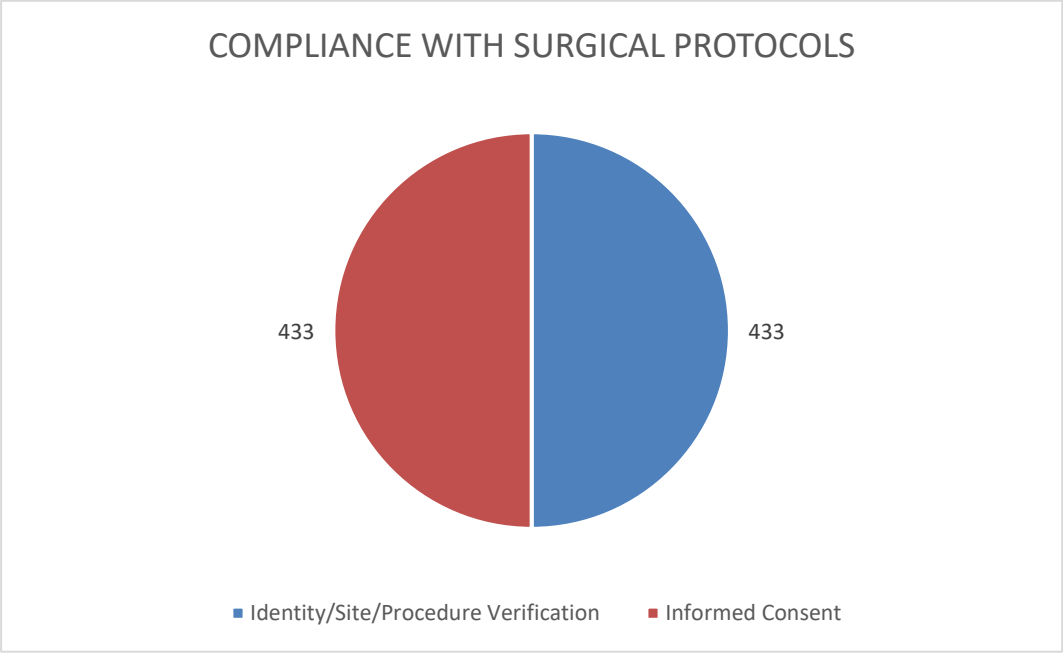
This indicates strong compliance with ethical and legal standards.

Identity, Site and procedure Verification:

100% compliance with WHO Surgical Safety Checklist.

Ensures correct patient, correct site, and correct procedure.

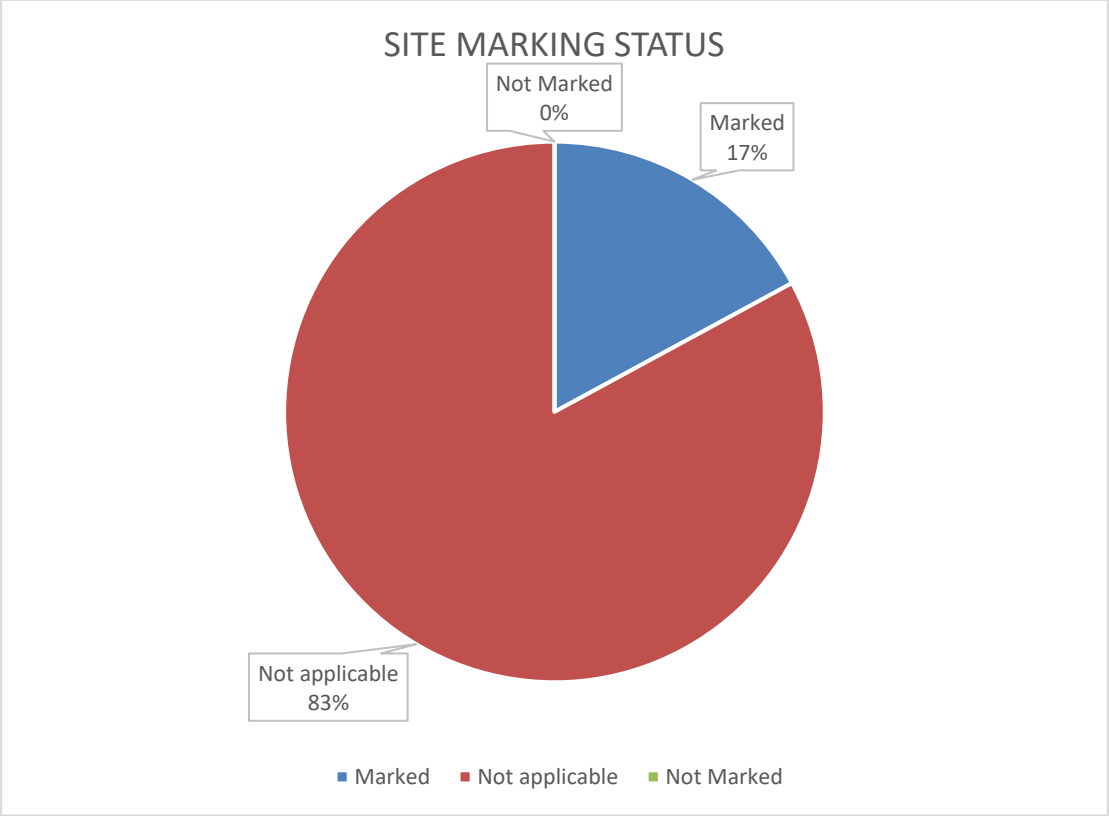
Category	Compliant	Non-Compliant
Identity/Site/Procedure Verification	433	0
Informed Consent	433	0



6. SITE MARKING

In a total of 433 patients, site marking was performed in 100% of applicable surgeries such as hernias before surgery. This indicates strict adherence to preoperative safety protocols, ensuring correct surgical site identification. Site marking in surgeries such as cholecystectomies may not be applicable.

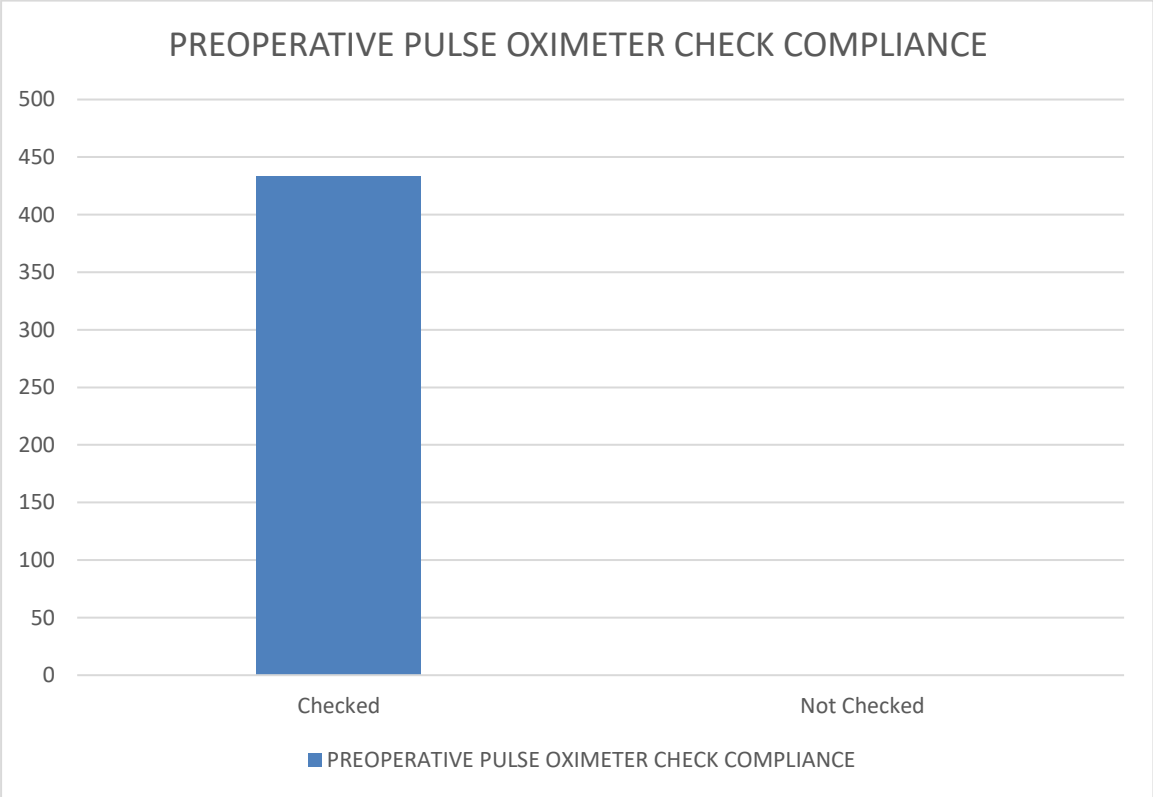
Status	Number of Patients
Marked	74
Not applicable	359
Not Marked	0



7. ANAESTHESIA MACHINE, MEDICATION & PULSE OXYMETRY CHECKS

In a total of 413 patients, 100% underwent a anaesthesia machine, medication & pulse oximeter check before surgery. This demonstrates strict adherence to perioperative monitoring protocols and reflects the importance of continuous patient safety measures.

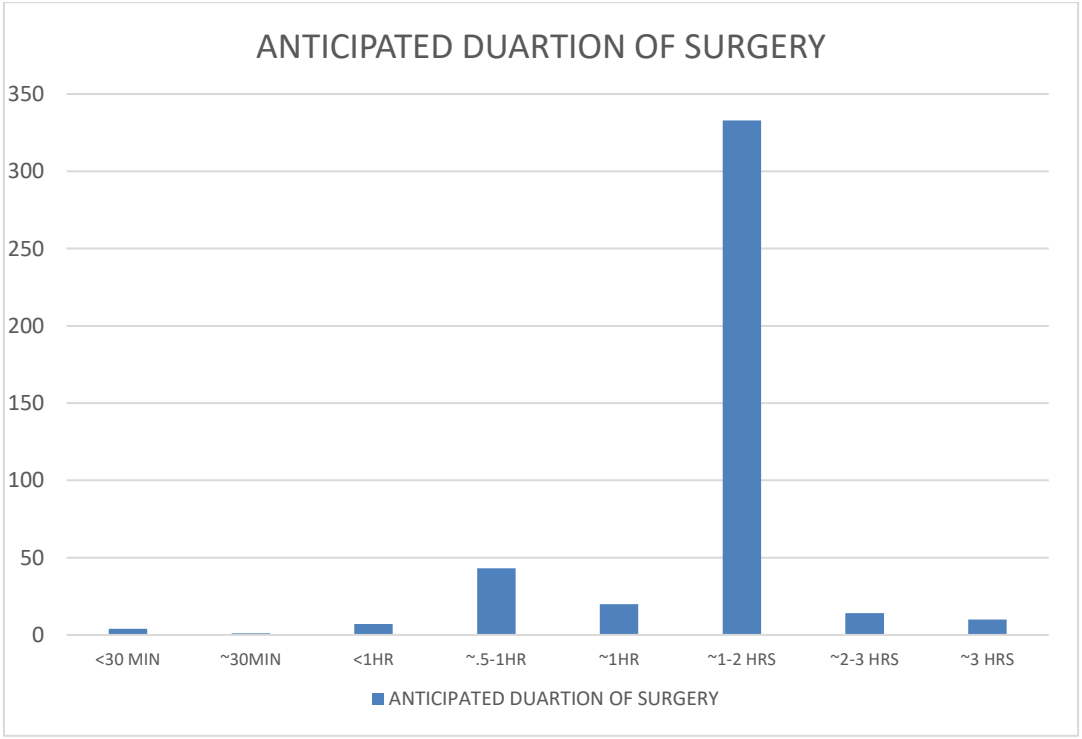
Status	Number of Patients
Checked	433
Not Checked	0



8. ANTICIPATED DURATION OF SURGERY

In this surgical audit comprising 433 patients, the majority of procedures were completed within 1 to 2 hours, with approximately 77% (333 cases) falling into this category. A smaller number of surgeries were shorter, including 0.5–1 hour procedures (43 cases) and less than 1 hour procedures (7 cases). Notably, only 14 cases extended to 2–3 hours, and 10 cases exceeded 3 hours, highlighting that most surgeries were of moderate duration. Very short procedures, such as those under 30 minutes (4 cases) and around 30 minutes (1 case), were rare. This distribution suggests that most general surgeries are completed within 1 to 2 hours, aligning with findings from various tertiary hospitals.

Anticipated Duration of Surgery	Count
<30 MIN	4
~30MIN	1
<1HR	7
~.5-1HR	43
~1HR	20
~1-2 HRS	333
~2-3 HRS	14
~3 HRS	10



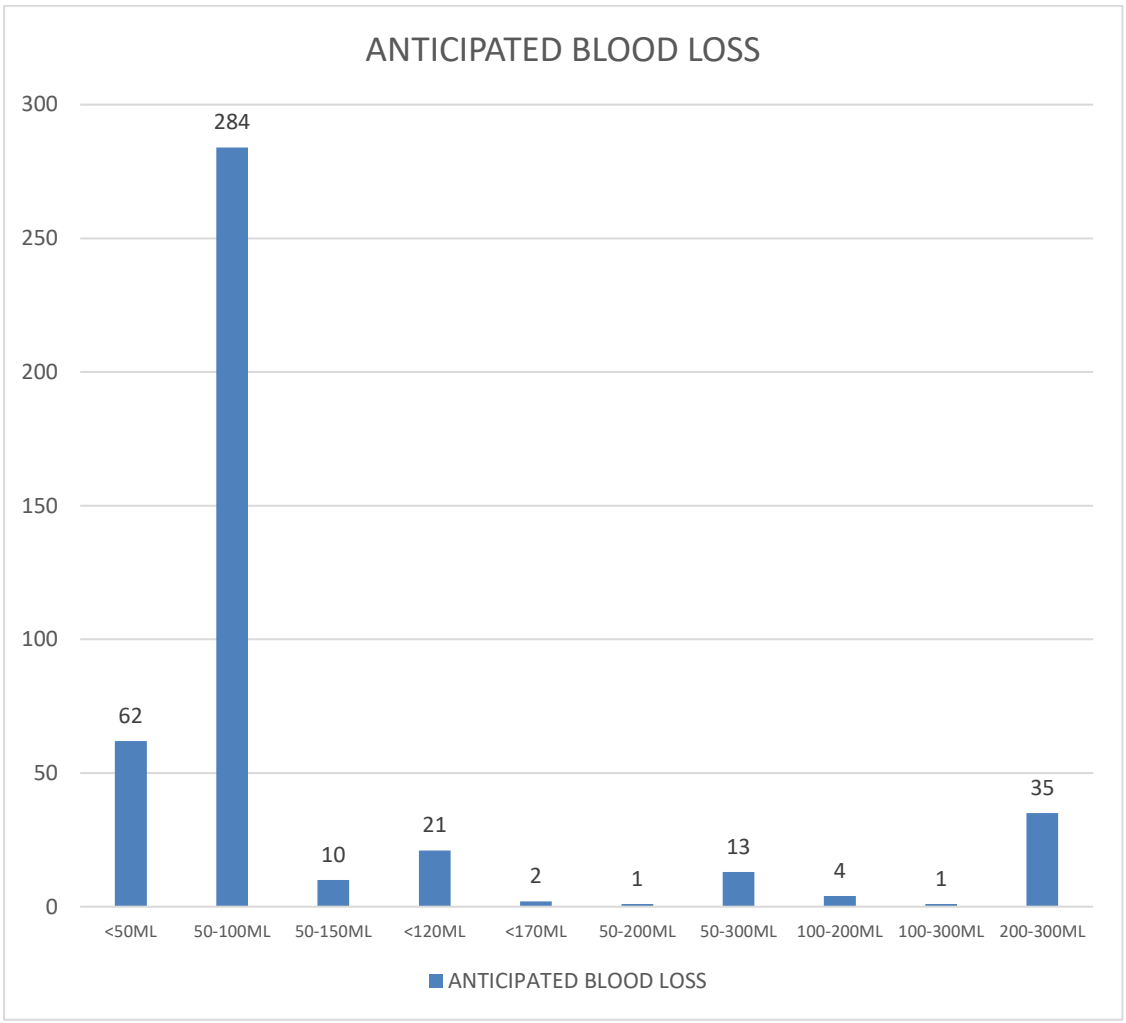
9. Anticipated Blood Loss

In this audit of elective surgeries, the majority of patients were anticipated to have minimal blood loss. Specifically, 346 patients were expected to lose less than 100 mL of blood, comprising those in the <50 mL and 50–100 mL categories. A smaller group of 10 patients fell within the 50–150 mL range, while an additional 7 patients had anticipated losses between 100 and 200 mL, derived from multiple overlapping categories such as <170 mL, 50–200 mL, and 100–200 mL.

Furthermore, 49 patients were predicted to experience moderate blood loss between 200 and 300 mL, as represented in the 50–300 mL, 100–300 mL, and 200–300 mL groups. Notably, 21 patients were documented under the <120 mL category, which also likely overlaps with the <100 mL range.

Overall, the data suggests that most elective surgeries were associated with low anticipated intraoperative blood loss.

Anticipated Blood Loss	**Frequency**
<50ML	62
50-100ML	284
50-150ML	10
<120ML	21
<170ML	2
50-200ML	1
50-300ML	13
100-200ML	4
100-300ML	1
200-300ML	35


ANTICIPATED BLOOD LOSS
300
250
200
150
100
50
0
284
62
10
21
2
1
13
4
1
35
<50ML
50-100ML
50-150ML
<120ML
<170ML
50-200ML
50-300ML
100-200ML
100-300ML
200-300ML
ANTICIPATED BLOOD LOSS

10. CONFIRMATION OF PATIENT DATA AND SURGICAL AUDIT FINDINGS

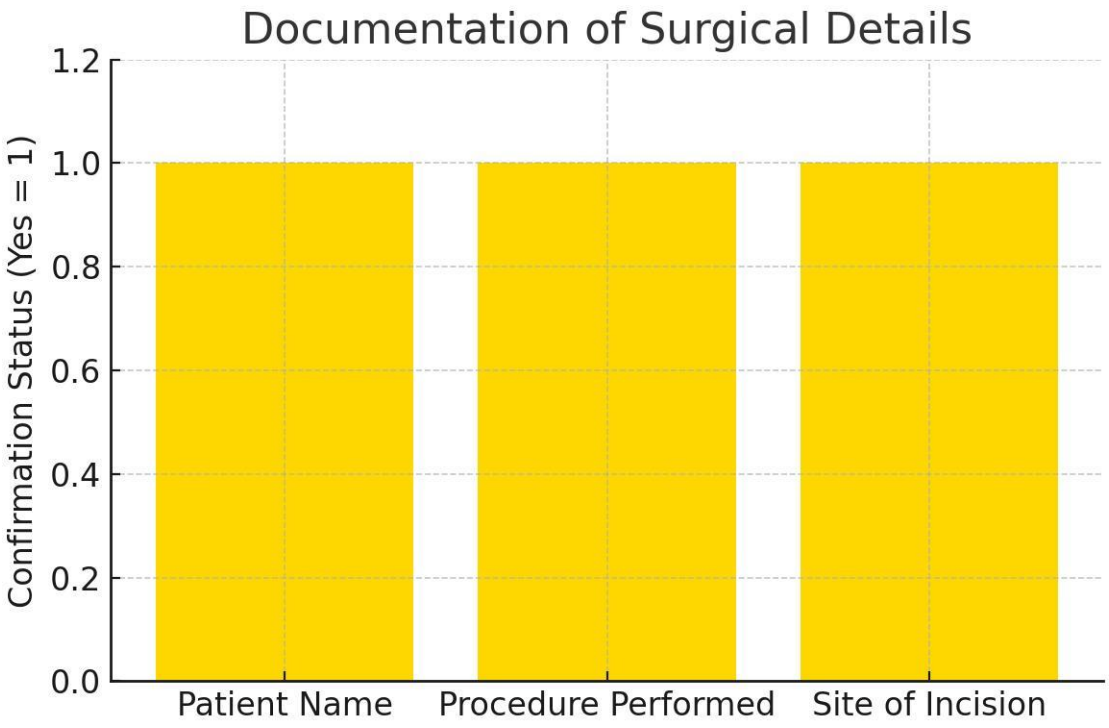
In a surgical audit involving 433 patients, all individuals had documented confirmation of the following key surgical details:

Patient Name

Procedure Performed

Site of Incision

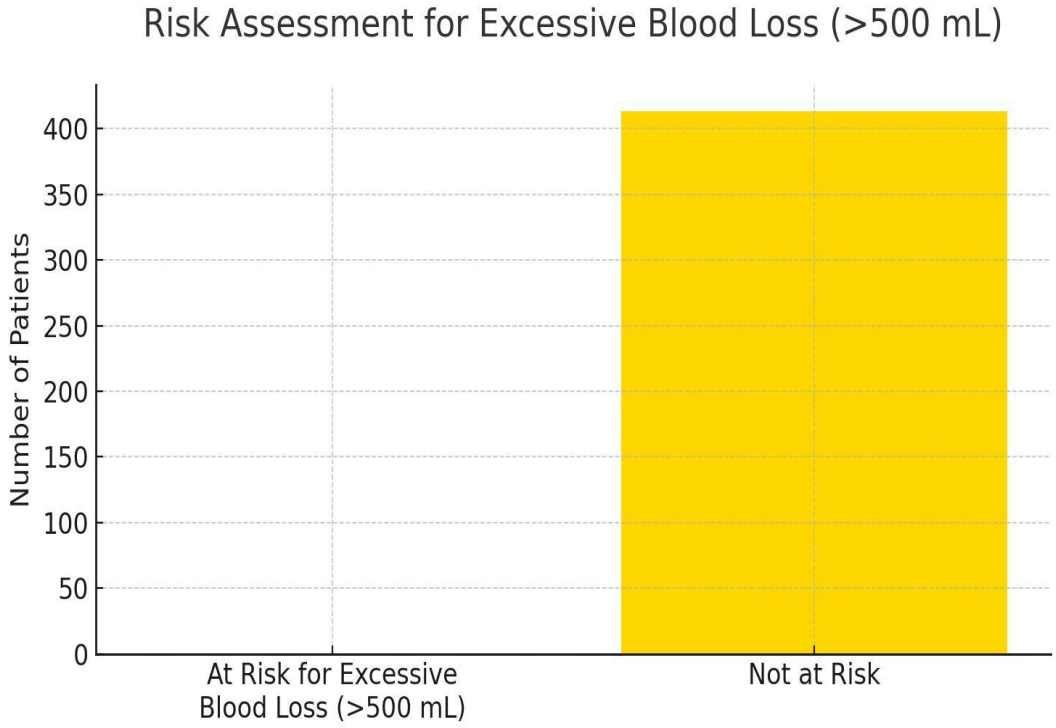
Surgical Detail	Confirmed in All Patients
Patient Name	Yes
Procedure Performed	Yes
Site of Incision	Yes



11. RISK OF BLOOD LOSS >500ML

In the surgical audit involving 433 patients, none were identified as at risk for excessive blood loss (>500 mL).

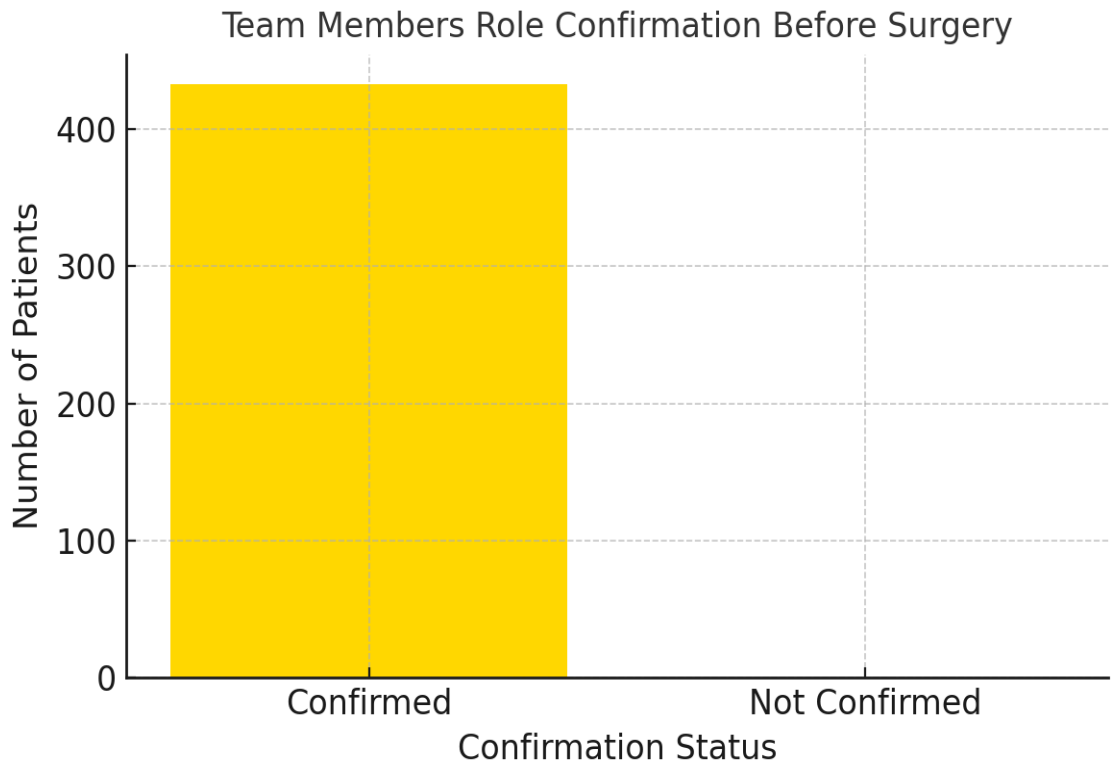
Risk Category	Number of Patients
At Risk for Excessive Blood Loss (>500 mL)	0
Not at Risk	433



12. TEAM MEMBERS AND THEIR ROLES

In this study, a detailed audit was conducted on 433 patients, all team members successfully confirmed their role in the operating theatre before surgery.

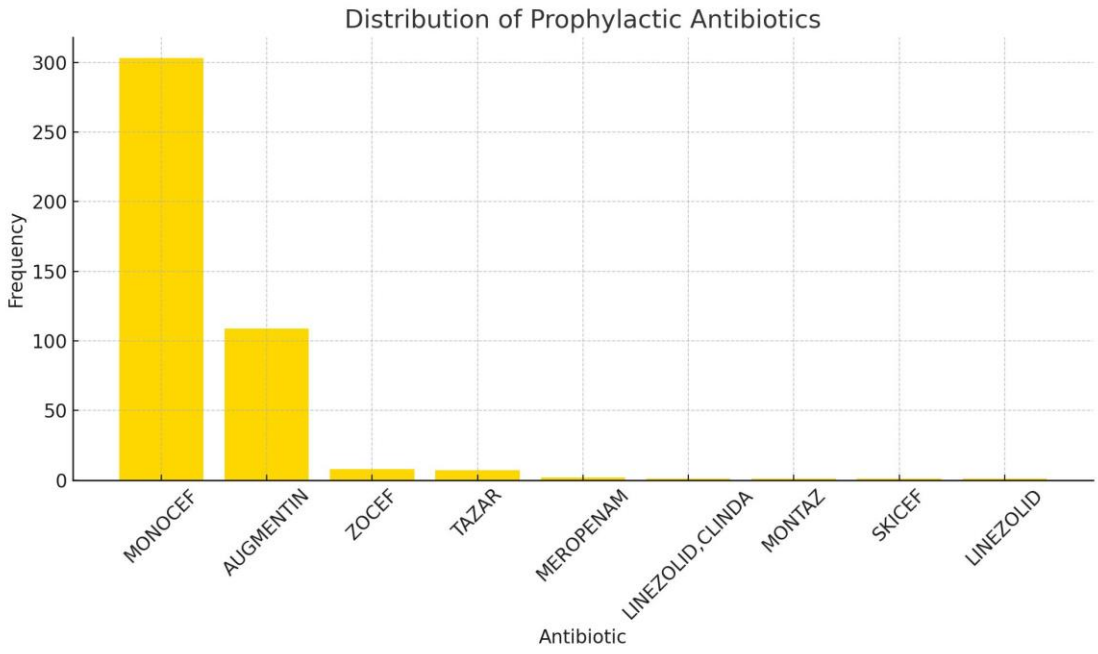
Role Confirmation	Number of Patients
Confirmed	433
Not Confirmed	0



13. Antibiotic Prophylaxis

All 433 patients in this study were successfully administered with IV antibiotics within 60 minutes of the commencement of surgery.

Prophylactic Antibiotic	Frequency
MONOCEF	303
AUGMENTIN	109
ZOCEF	8
TAZAR	7
MEROPENAM	2
LINEZOLID,CLINDA	1
MONTAZ	1
SKICEF	1
LINEZOLID	1

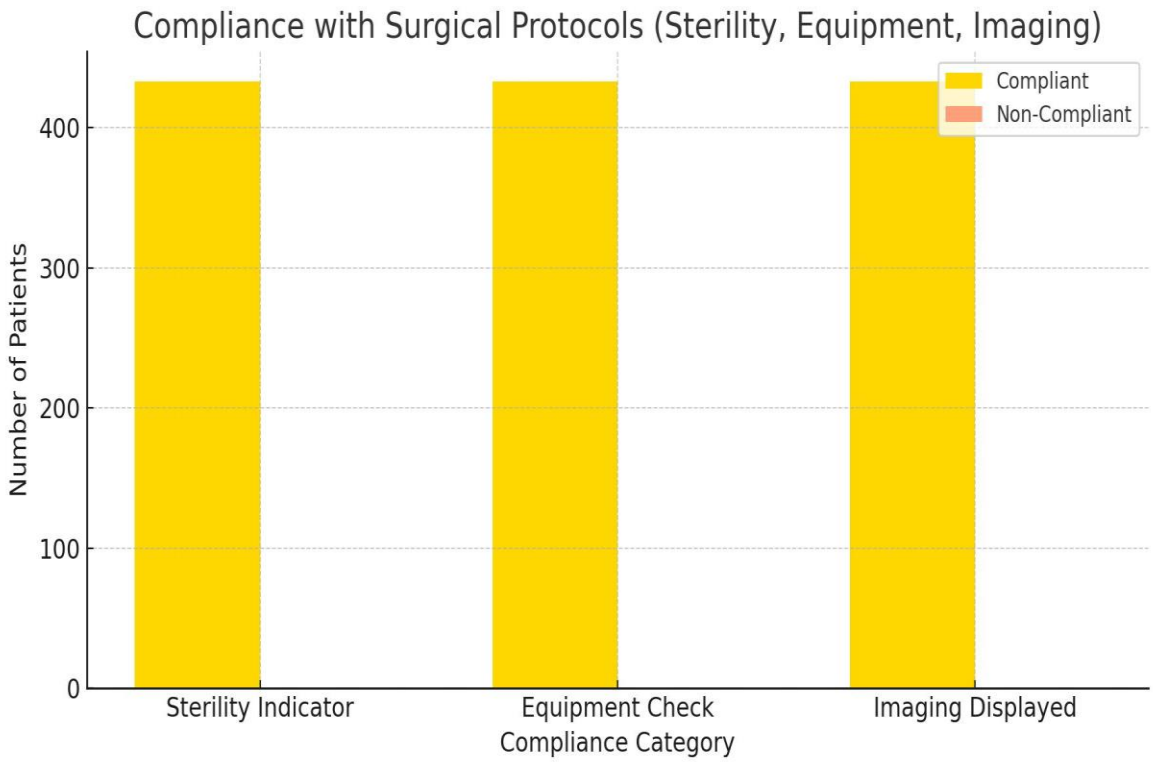


14. Sterility confirmation, Equipment issues, &Essential imaging

Sterility indicators were checked before the commencement of surgery in all of the 433 patients and found to be satisfactory.

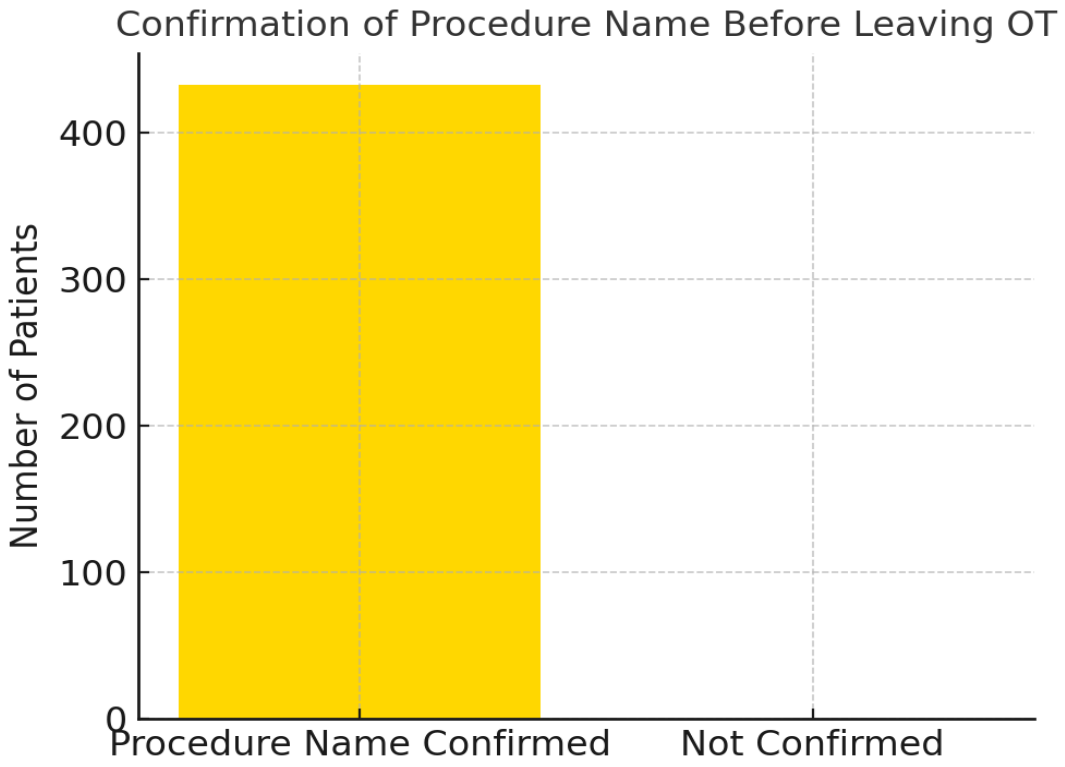
All equipment was checked to have no issues before the commencement of surgery in all 433 cases

Essential imaging was displayed for all 433 patients in the operating theatre.



15. Confirmation of the name of the procedure

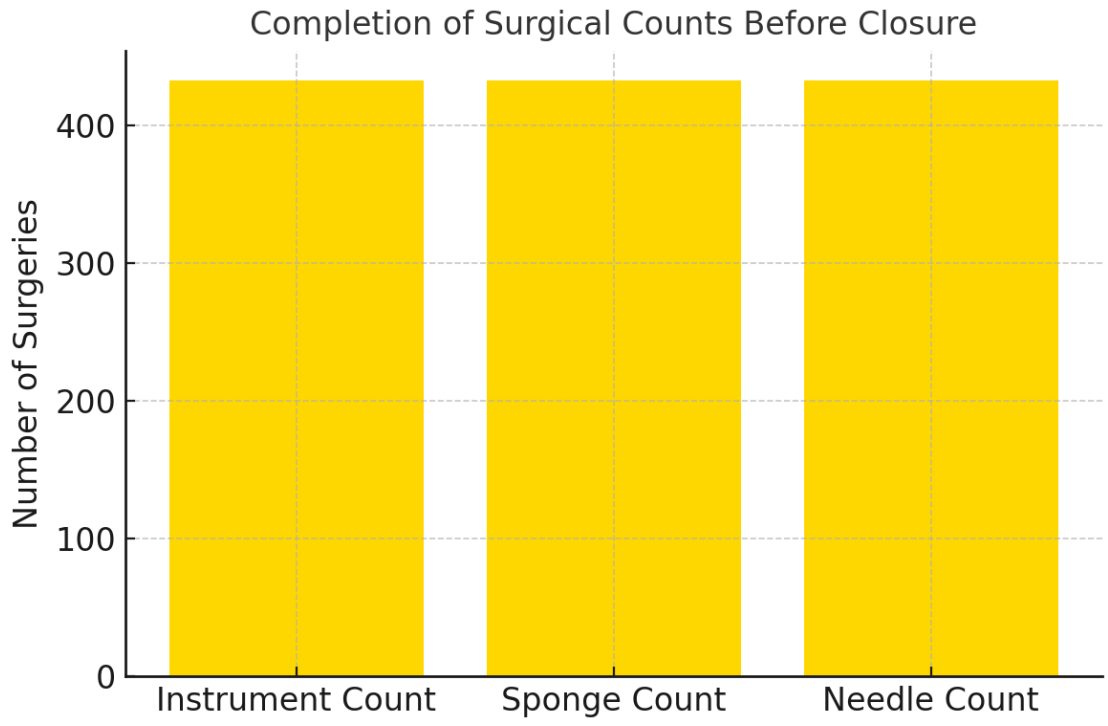
All 433 patients were confirmed for the name of procedure performed before the patient leaves the operating theatre



16. Instrument, Sponge, Needle Counts

In this study, instrument , sponge and needle counts were done before final closure of all 433 surgeries and counts were found to be complete in all of the cases.

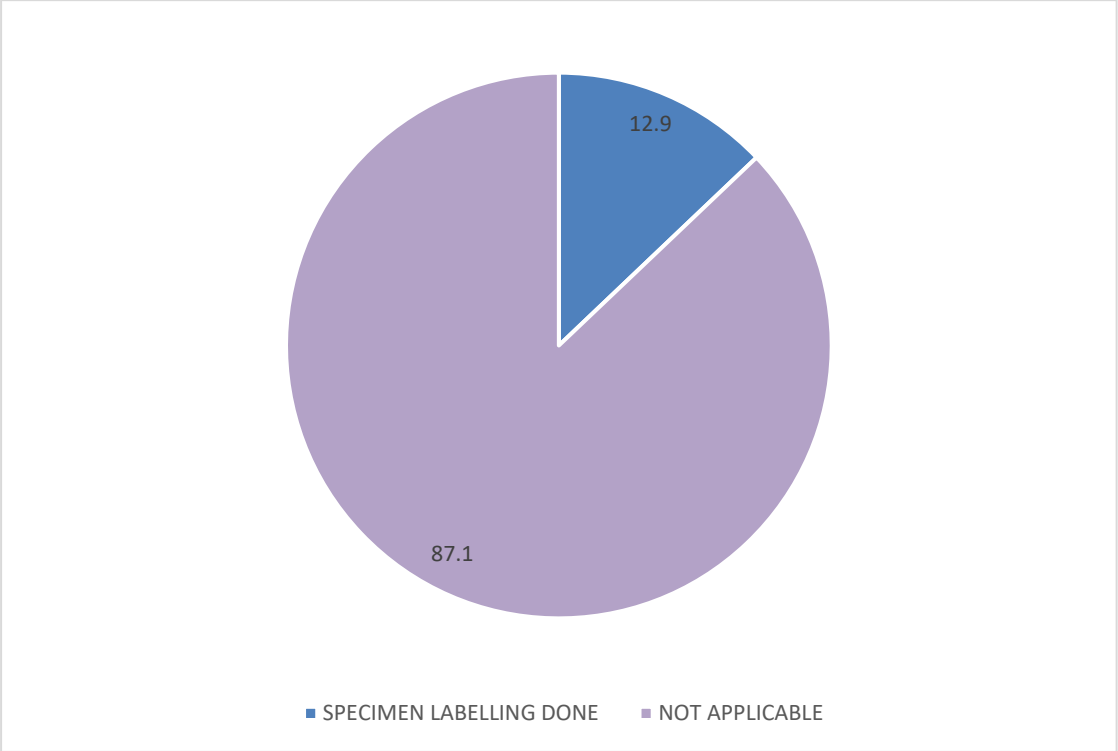
Counts	Number of Surgeries	Completion Status	Percentage (%)
Instrument Count	433	Complete	100
Sponge Count	433	Complete	100
Needle Count	433	Complete	100



17. Specimen Labelling

In this study, out of 433 cases, specimen labelling was done all applicable 377 cases, and rest were non applicable cases in which no specimen was available.

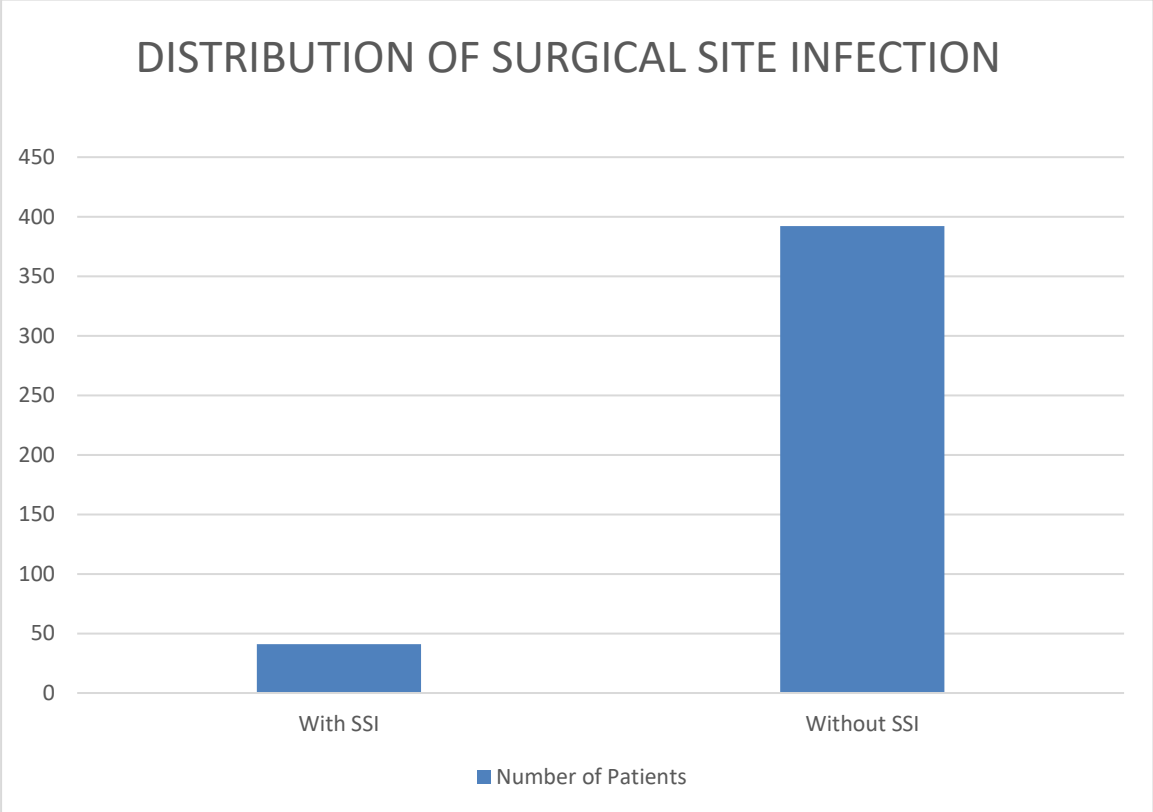
Category	Number of Cases	Percentage (%)
Specimen Labelling Done	377	87.1
Not Applicable (No Specimen)	56	12.9



18. SURGICAL SITE INFECTION

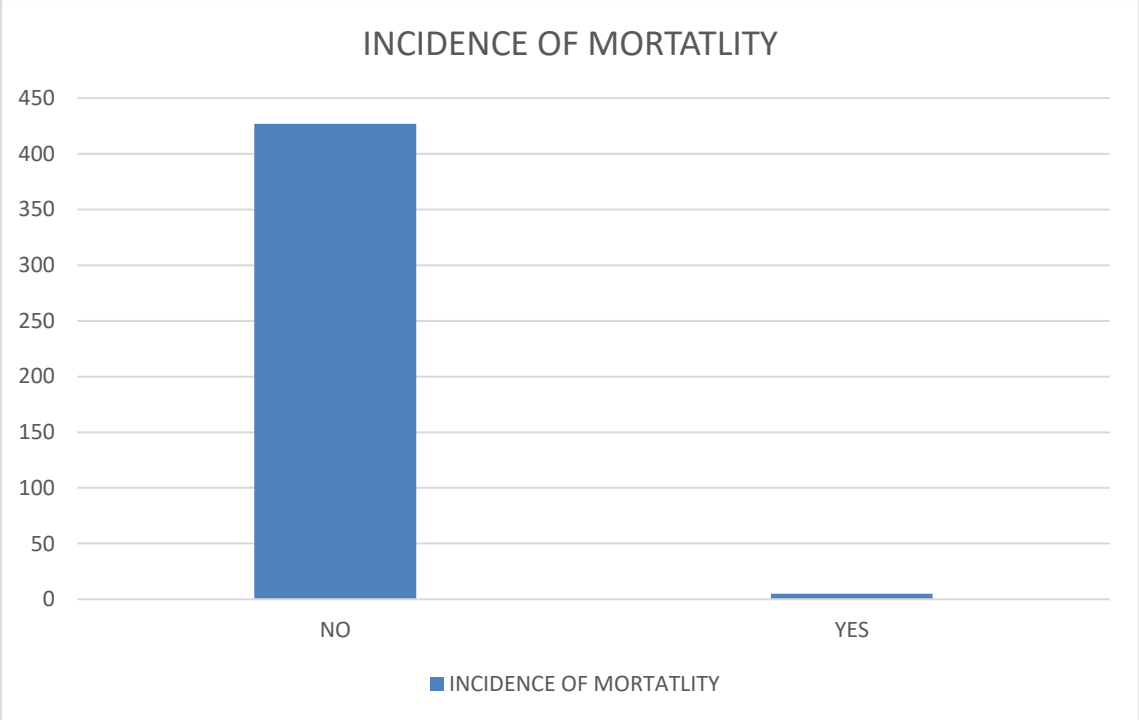
In this study, out of 433 patients, 41patients (9.47%) developed SSI, while 392 patients (90.53%) did not experience this complication.

SSI Status	Number of Patients	Percentage (%)
With SSI	41	9.47%
Without SSI	392	90.53%
Total	**433**	**100%**



19. INCIDENCE OF MORTALITY

INCIDENCE OF MORTATLITY	FREQUENCY
NO	427
YES	5
TOTAL	433



The mortality rate among the study population was low, with only 5 out of 433 patients (1.15%) succumbing during the study period. The vast majority (98.85%) of patients survived, indicating favourable overall outcomes.

DISCUSSION

DISCUSSION

Surgical audits are critical quality improvement tools designed to evaluate and enhance patient safety, clinical outcomes, and adherence to standardized protocols in the operating theatre. The World Health Organization (WHO) emphasizes the use of the Surgical Safety Checklist and structured documentation to minimize complications and ensure safe perioperative practices. This audit was conducted to analyze various perioperative parameters across 433 general surgical cases at a tertiary care center. It aimed to assess the distribution of patient demographics, operative characteristics, compliance with safety protocols, and immediate outcomes such as surgical site infections and mortality.

1. Age Distribution

The distribution of age in this surgical audit reveals a concentration of cases between 31–60 years (65.9%), highlighting a predominance in the middle-aged demographic. This trend is consistent with the natural history of many general surgical conditions such as gallstone disease, hernias, and appendicitis, which often become symptomatic in middle adulthood(46)[Shaffer et al,2006]. Age-related physiological resilience and better perioperative outcomes may also contribute to higher surgical uptake in this group. Global surgery data affirm that the working-age population (30–60 years) forms the largest surgical volume in both elective and emergency scenarios(47)[Meara et al,2015].

2. Gender Distribution

Male predominance (65.2%) observed in this study aligns with several surgical audits from India and other countries, where cultural and socioeconomic factors influence healthcare-seeking behavior(46)[Shaffer et al,2005]. Men are more likely to present with advanced disease or complications, increasing the probability of surgical intervention. However, in conditions like gallstone disease, females are generally at greater risk due to hormonal and metabolic influences. This variation emphasizes the role of both biological and social determinants in surgical presentation.

3. Type of Surgery

Laparoscopic procedures were predominant (56.8%), aligning with the global shift towards minimally invasive surgery, which offers faster recovery, less postoperative pain, and reduced hospital stay(48). The conversion rate to open surgery (2.3%) reflects excellent laparoscopic expertise, as rates up to 5–10% are considered acceptable in literature, especially in cases with inflammation or adhesions(49). Open surgery still accounted for 40.9%, possibly due to emergency settings or resource limitations.

4. Type of Anaesthesia

General anaesthesia was used in 76% of cases, particularly in laparoscopic and complex open surgeries. This preference aligns with safety protocols for airway protection and muscle relaxation during prolonged procedures. Spinal anaesthesia (23%) is increasingly being used in select surgeries like hernias and lower abdominal cases, owing to its safety, cost-effectiveness, and postoperative pain control(50,51). Studies have demonstrated comparable outcomes and even reduced complication rates in certain cases under regional anaesthesia.

5.Informed Consent and Site Verification

A 100% compliance rate for informed consent and surgical site verification reflects strong adherence to ethical and legal protocols.[Haynes et al,2009] Such compliance reduces "never events" and improves trust and safety[De Vries et al,2010](52,53).

6.Site Marking

Site marking was performed in 100% of applicable cases (e.g., hernias), reflecting strict preoperative safety standards, crucial for preventing wrong-site surgeries[Panesar et al,2011](54).

7.Anaesthesia Machine and Pulse Oximetry Checks

All 433 patients had machine, medication, and oximeter checks before surgery. This adherence is vital to prevent equipment-related errors and ensure perioperative safety[Weller et al,2013][Merry et al,2011][(55,56).

8.Anticipated Duration of Surgery

Majority of surgeries lasted 1–2 hours (77%). Efficient timing is correlated with reduced SSI, blood loss, and anesthesia-related complications[Cheng et al,2017][Kahokehr et al,2011](57,58).

9.Risk of Blood Loss >500 mL

No patients were anticipated to have blood loss >500 mL. This underscores the overall low-risk nature of the performed procedures and strong surgical control[Wu et al,2010][Shander,2004]](59,60).

10.Team Role Confirmation

All 433 surgical teams confirmed roles before starting. Role clarity enhances communication, accountability, and reduces errors in high-risk environments[Lingard et al,2004][Hull et al ,2011](61,62).

11.Antibiotic Prophylaxis

Prophylactic antibiotics were given in 100% cases, primarily Monocef and Augmentin. Timely pre-incision prophylaxis reduces SSI significantly when given within 60 minutes before incision[Allegranzi et al,2016][Bratzler et al,2013](63,64).

12.Sterility, Equipment & Imaging

Sterility indicators, equipment integrity, and imaging display were confirmed in all cases, supporting WHO surgical standards and reducing intraoperative surprises[WHO guidelines for safe surgery,2009](65).

13.Confirmation of Surgical Details

Patient name, procedure, and incision site were confirmed in 100% of cases, emphasizing surgical discipline and patient safety[]Clarke.,2005][Makary et al,2007](66,67).

14.Instrument, Sponge, Needle Counts

All surgical counts were 100% complete. Count accuracy is essential to avoid retained surgical items, a major preventable error[Egorova et al,2008](68).

15.Specimen Labelling

Out of 433 cases, specimen labelling was done in all applicable 377 (87.1%) cases, confirming proper histopathological workflows and reducing diagnostic errors[]Carmack et al,2024][Layfield and Anderson,2010](69,70).

16.**Safety Protocol Compliance**

This study reported 100% compliance with WHO Surgical Safety Checklist, informed consent, site marking (where applicable), and equipment checks. Literature strongly supports that checklist adherence significantly reduces postoperative complications and mortality(52). Patient identity, site, and procedural verification are cornerstones of modern perioperative care and reduce the risk of "never events" such as wrong-site surgery(71).

17.Duration of Surgery

Most procedures (77%) were completed within 1–2 hours, which is consistent with standard operative times for common general surgical interventions. Shorter durations are typically associated with lower rates of complications and better recovery outcomes. Prolonged operative time has been linked to increased risk of wound infection, blood loss, and anesthetic complications(72)[Cline et al,2020]. Time efficiency also reflects surgical team proficiency and adherence to enhanced recovery protocols(73)[Gowd et al,2020].

18.Anticipated Blood Loss

The majority of patients (79.7%) had anticipated blood loss under 100 mL, reflecting careful surgical technique and the dominance of minimally invasive approaches in the cohort. Anticipated blood loss is a strong surrogate for operative complexity, and low estimates suggest low intraoperative risk(74)[Charalambides et al,2022]. Minimizing

blood loss reduces the need for transfusions, which are independently associated with postoperative complications(75)[Bernar et al,2009]. Modern electrocautery tools, vessel sealing systems, and meticulous hemostasis contribute to this outcome.

19. Surgical Site Infections (SSI)

An SSI rate of 9.47% was noted, which is acceptable but emphasizes the need for continued vigilance. Factors influencing SSI include type of procedure (open vs laparoscopic), operative time, and patient comorbidities. The universal administration of prophylactic antibiotics within 60 minutes preoperatively in all cases aligns with WHO recommendations and has been shown to reduce SSI rates significantly(63)[Allegranzi et al,2016]. Strict adherence to asepsis, proper wound closure, and postoperative care are critical in preventing these infections(76)[Hedrick et al,2005].

20.Mortality

The observed mortality rate of 1.15% is well within expected limits for general surgical procedures. Literature reports perioperative mortality rates between 0.5% to 2.0%, depending on patient comorbidities and surgery complexity(77)[Pearse et al,2012]. This low rate reflects effective perioperative management, anesthetic care, infection prevention, and surgical competence. Mortality audits are essential for quality improvement and risk stratification. Early identification of high-risk patients and standardized protocols significantly reduce mortality rates in surgical units(78)[Biccard et al,2018].

SUMMARY

SUMMARY OF FINDINGS

1. **Demographics:**
    - Most patients were in the 31–60 year age group (65.9%), indicating a predominance of middle-aged individuals undergoing surgery.
    - Male patients accounted for 65.2% of cases, suggesting gender disparity in healthcare-seeking behavior and disease prevalence.
2. **Type of Surgery & Anaesthesia:**
    - Laparoscopic procedures were performed in 56.8% of cases, reflecting a preference for minimally invasive techniques.
    - The conversion rate to open surgery was low (2.3%), while 40.9% of surgeries were entirely open.
    - General anaesthesia was used in 76% of cases, with spinal anaesthesia accounting for 23%.
3. **Safety Protocol Compliance:**
    - 100% compliance was achieved in key safety measures, including informed consent, site verification, machine and oximeter checks, role confirmation, and sterility assurance.
    - Surgical details such as patient name, procedure, and incision site were confirmed preoperatively in all cases.
    - The WHO Surgical Safety Checklist was implemented in every case.
4. **Intraoperative Parameters:**
    - Most surgeries were completed within 1–2 hours (77%), aligning with international benchmarks.
    - No patient was anticipated to lose more than 500 mL of blood, and nearly 80% had an estimated loss of less than 100 mL.
5. **Count Accuracy and Specimen Labelling:**
    - Instrument, sponge, and needle counts were 100% complete across all surgeries.
    - Specimen labelling was performed in all applicable cases (377 of 433; 87.1%), with the remainder not requiring specimen handling.
6. **Outcomes:**
    - The surgical site infection (SSI) rate was 9.47%, which is within acceptable limits.
    - A mortality rate of 1.15% was recorded, consistent with expected global standards for general surgery.

CONCLUSION

CONCLUSION

This surgical audit highlights a high level of compliance with established perioperative safety practices and confirms the implementation of WHO-recommended protocols in a tertiary care setting. The majority of surgeries were safely performed using laparoscopic techniques with low anticipated blood loss and efficient operative times. The audit revealed near-universal adherence to critical safety measures such as consent verification, role confirmation, and instrument counts, all of which are instrumental in reducing avoidable complications and enhancing patient outcomes.

The SSI and mortality rates observed were within acceptable international norms, reinforcing the quality of surgical care delivered. However, ongoing emphasis on specimen labelling, operative documentation, and SSI prevention strategies remains essential. Overall, the audit supports the effectiveness of structured surgical protocols in improving clinical efficiency, team coordination, and patient safety in routine surgical practice.

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ANNEXURES

PROFORMA

SECTION-A

Patient Information:

- NAME:
- AGE:
- GENDER:
- ADDRESS:
- CONTACT NUMBER:
- MEDICAL RECORD NUMBER:
- HOPI:
- PAST HISTORY:
- FAMILY HISTORY:
- PERSONAL HISTORY:

GENERAL EXAMINATION:

- GENERA CONDITION-
- BP-
- PR-
- RR-
- SpO2-
- P/I/C/C/L/E-

CVS EXAMINATION:

RESPIRATORY EXAMINATION:

PER ABDOMEN EXAMINATION:

CNS EXAMINATION:

Clinical Presentation:

- Presenting Complaints:
- History of presenting illness:

Diagnostic Findings:

1. Imaging:

- X-ray Chest:

- USG Whole Abdomen:
- CT Abdomen:

2. Laboratory Tests:

- CBC:
- LFT
- KFT
- PT/INR
- URINE R/M
- BLOOD GROUP
- VIRAL MARKERS

SECTION-B

Procedure Name

Primary Surgeon

Diagnosis

Date of Surgery

Preoperative Antibiotic Given

Surgical Approach ☐ Laparoscopic ☐ Open

Anaesthesia Type ☐ General ☐ Spinal ☐ Local ☐ Other

Intraop Findings:

WHO SURGICAL SAFETY CHECKLIST:

- **Before induction of anaesthesia: Yes/No**
- **Before skin incision: Yes/No**
- **Before patient leaves operating room:Yes/No**

Post op recovery:

Post op complications(if any):

Post op morbidity/mortality:

Follow-up complications(if any):

संतोष मेडिकल कॉलेज एवं अस्पताल (गाजियाबाद)
<u>सहमति पत्र (सूचित)</u>

मैं _____ बेटा/ बेटी/ पत्नी_____निवासी _____ घोषणा करता हूं कि डॉ ._____, ने मुझे मेरी भाषा में अपने अध्ययन "**SURGICAL AUDIT OF THE DEPARTMENT OF SURGERY IN A TERTIARY CARE CENTRE: INCIDENCE OF SSI AND OTHER COMPLICATIONS WITH IMPLEMENTATION OF WHO SURGICAL SAFETY CHECKLIST "** के उद्देश्य के बारे में, और अध्ययन के दौरान अपनाई जाने वाली विभिन्न प्रयोगशाला जांच के बारे में सूचित कर दिया है। मुझे अध्ययनकी अवधि और उसके दौरान अपनाए जाने वाले निर्देश भी मेरी भाषा मे समझा दिए गए हैं| मैं उपरोक्त अध्ययन में बिना किसी दबाव के दाखिला ले रहा हूं और पूर्ण सहमति दे रहा हूं | सन्तोष अस्पताल, गाजियाबाद में अपने आगे के उपचार पर बिना प्रतिकूल प्रभाव डाले इस अध्ययन से और प्रयोगशाला जांच की प्रकृति से मैं जब चाहूँ बाहर जाने के अपने अधिकार को सुरक्षित रख रहा हूं|

रोगी / रोगी के रिश्तेदार के हस्ताक्षर डॉक्टर के हस्ताक्षर

नाम

दिनांक:

मेरी उपस्थिति में मरीज ने पूरी तरह से डाकटर के बताए गए अध्ययन और निर्देशों को समझने के बादअपनी स्वतंत्र इच्छा से ऊपर के फार्म पर हस्ताक्षर किए हैं ।

हस्ताक्षर:

नाम: डॉ0 हर्ष आर्यन

पदनाम: पीजी

शल्य चिकित्स विभाग

INFORMED CONSENT

I _____ Son/Daughter/Wife of _____ resident of _____hereby declare that I give my full, free and voluntary informed consent in the thesis - "**SURGICAL AUDIT OF THE DEPARTMENT OF SURGERY IN A TERTIARY CARE CENTRE: INCIDENCE OF SSI AND OTHER COMPLICATIONS WITH IMPLEMENTATION OF WHO SURGICAL SAFETY CHECKLIST ".** I**,** Dr._____ has informed me to my full satisfaction, in the language I understand, about the purpose, nature of study and various laboratory investigations for the study to be carried out. I have been informed about the duration of the study and instructions to be followed during the study period.

I give full consent for being enrolled in the above study and I reserve my rights to withdraw from this study, whenever I wish without prejudice of my right to undergo further treatment at Santosh Hospital, Ghaziabad U.P.

Patient's/ Patient's relative's signature Doctors signature
Or thumb impression

Name: Date:

We have witnessed that the patient signed the above form in the presence of his free will after fully understanding its content.

Signature of Witness

Name

Signature of Investigator
Name: Dr. Harsh Aryan
Designation: PG Department of General Surgery
Contact No.- 8564066572

SANTOSH MEDICAL COLLEGE & HOSPITAL

Details of Patient Information Sheet

Human Subject Research Proposal

1) Identifying Data

Name of Researcher: Dr. Harsh Aryan

Department: Department of General Surgery

Title of Project**: "SURGICAL AUDIT OF THE DEPARTMENT OF SURGERY IN A TERTIARY CARE CENTRE: INCIDENCE OF SSI AND OTHER COMPLICATIONS WITH IMPLEMENTATION OF WHO SURGICAL SAFETY CHECKLIST "**

2) Description of Human Subjects Safeguards and Rights:

A) Possible psychological or physical risk or discomfort, involved in research

Yes □ NO □ (if no, skip item B)

If Yes, answer the following

Why necessary?

1. To have the common disease
2. Specificity and sensitivity of the treatment

B) Make sure the following questions are answered in your research proposal on collection of Data:

1) When will it take place?

April 2024- April 2025

2) What length of time needed for complete examination of the patient?

Approx 1 hour.

3) What period of time needed?

Approx 1 year.

4) Which specific place within institution?

Department of Surgery.

5) How much population required including number of subjects?

6) Name of instrument to be used for data collection?
USG findings, CT Scan, Laboratory Tests.

7) Methodology to be used (write details)?

- A detailed history of all patients will be taken and a thorough clinical examination will be done. All patients will be observed in terms of surgery performed with type of anaesthesia used, if WHO surgical safety checklist followed, any intra-op and post-op complications, any post-op morbidity/mortality
- The analyzed data will be correlated with other series in literature and discussed. A master chart dealing with all aspects will be designed and presented. A proforma will be used for the study purpose.

C) Will Subjects be given research results if they so request?

Yes □ No □

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ETHICAL COMMITTEE CLEARANCE

SANTOSH
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(Established u/s 3 of the UGC Act, 1956)

F. No. SU/R/2023/2489[44] Dated: 26.09.2023

Subject: Grant of Ethical Clearance for **Thesis Protocol** Topic **"SURGICAL AUDIT OF THE DEPARTMENT OF SURGERY IN A TERTIARY CARE",** submitted by **Dr. HARSH ARYAN,** MD/MS student of Batch 2022-2023, Department of **GENERAL SURGERY.**

*****

With reference to his/her request for grant of Ethical Clearance for the Thesis Protocol entitled **"SURGICAL AUDIT OF THE DEPARTMENT OF SURGERY IN A TERTIARY CARE", Dr. HARSH ARYAN** is informed that the **Thesis Protocol** submitted by him/her was considered by the **Screening Committee** of the Santosh Medical College & Hospital in its meetings held on 17.07.2023 to 28.07.2023. The recommendations of the **Screening Committee** were considered in detail by the **Institutional Ethics Committee** in its meeting held on **23.09.2023** and the same was **approved** by the **Ethics Committee.**

He /She is informed accordingly for further necessary action.

[Dr. NARESH SHARMA]
REGISTRAR

SANTOSH "DEEMED TO BE UNIVERSITY" REGISTRAR GHAZIABAD, NCR DELHI

Dr. HARSH ARYAN
MD/MS student of batch 2022-2023
Department of GENERAL SURGERY
Email: harsharyan2100@gmail.com

Copy to:

1. The Vice Chancellor
2. The Dean, SMC&H
3. The Dean – Academics
4. The Dean – Research
5. The Director - IQAC
6. Dr. Shalabh Gupta (Guide)
7. HOD of GENERAL SURGERY